IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE DISTRICT OF COLUMBIA, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF IOWA, THE STATE OF LOUISIANA, THE STATE OF MARYLAND, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, THE STATE OF WASHINGTON, and THE STATE OF WISCONSIN *EX REL.* [UNDER SEAL],<br><br>Plaintiffs,<br><br>v.<br><br>[UNDER SEAL],<br><br>Defendants. | : | Civil Action No. 12-cv-4239<br><br>Filed In Camera And Under Seal In Accordance With The False Claims Act, 31 U.S.C. § 3730(b)(2)<br><br>Do Not Place In Press Box<br>Do Not Enter on PACER<br><br>Jury Trial Demanded |

FILED
MAR 25 2014
MICHAEL E. KUNZ, Clerk
By _____ Dep. Clerk

**SECOND AMENDED COMPLAINT**

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| THE UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE DISTRICT OF COLUMBIA, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF IOWA, THE STATE OF LOUISIANA, THE STATE OF MARYLAND, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, THE STATE OF WASHINGTON, and THE STATE OF WISCONSIN *EX REL.* JESSE POLANSKY, M.D., M.P.H.,<br>Plaintiffs,<br><br>v.<br><br>EXECUTIVE HEALTH RESOURCES INC., UNITEDHEALTH GROUP INCORPORATED, UNITED HEALTHCARE SERVICES, INC., OPTUM, INC., OPTUMINSIGHT HOLDINGS, LLC, OPTUMINSIGHT, INC., COMMUNITY HOSPITAL OF THE MONTEREY PENINSULA, and YALE-NEW HAVEN HOSPITAL, INC.,<br>Defendants. | : | Civil Action No. 12-cv-4239<br><br>Filed In Camera And Under Seal In Accordance With The False Claims Act, 31 U.S.C. § 3730(b)(2)<br><br>Do Not Place In Press Box<br>Do Not Enter on PACER<br><br>Jury Trial Demanded |

**SECOND AMENDED COMPLAINT**

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1. Plaintiff relator Jesse Polansky, M.D., M.P.H. brings this action on behalf of the United States of America as well as the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Washington, and the State of Wisconsin (hereinafter collectively referred to as "Plaintiff States") against:

(a) Executive Health Resources, Inc., UnitedHealth Group Incorporated, United HealthCare Services, Inc., Optum, Inc., OptumInsight Holdings, LLC, and OptumInsight, Inc. for violations of the federal False Claims Act (31 U.S.C. §§ 3729 *et seq.*), the California False Claims Act (Cal. Gov't. Code §§ 12650 *et seq.*), Colorado Medicaid False Claims Act (Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq.*), Connecticut False Claims Act (Conn. Gen. Stat. §§ 17b-301b *et seq.*), Delaware False Claims and Reporting Act (Del. Code Ann. tit. 6, §§ 1201 *et seq.*), District of Columbia False Claims Act (D.C. Code Ann. §§ 2-308.13 *et seq.*), Florida False Claims Act (Fla. Stat. §§ 68.081 *et seq.*), the Georgia State False Medicaid Claims Act (Ga. Code Ann. §§ 49-4-168 *et seq.*), Hawaii False Claims Act (Haw. Rev. Stat. §§ 661-21 *et seq.*), Illinois False Claims Act (740 Ill. Comp. Stat. Ann. 175/1 *et seq.*), Indiana False Claims and Whistleblower Protection Act (Ind. Code §§ 5-11-5.5-1 *et seq.*), Iowa False Claims Act (Iowa Code §§ 685.1 *et seq.*), Louisiana Medical Assistance Programs Integrity Law (La. Rev. Stat. Ann. §§ 46:438.1 *et seq.*), Maryland False Health Claims Act (Md. Code Ann., Health-General

§§ 2-601 *et seq.*), Massachusetts False Claims Law (Mass. Ann. Laws. ch. 12, §§ 5A *et seq.*), Michigan Medicaid False Claims Act (Mich. Comp. Laws §§ 400.601 *et seq.*), Minnesota False Claims Act (Minn. Stat. §§ 15C.01 *et seq.*), Montana False Claims Act (Mont. Code Ann. §§ 17-8-401 *et seq.*), Nevada False Claims Act (Nev. Rev. Stat. §§ 357.010 *et seq.*), New Jersey False Claims Act (N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*), New Mexico Medicaid False Claims Act (N.M. Stat. Ann. § 27-14-1 *et seq.*), New York False Claims Act (N.Y. State Fin. Law §§ 187 *et seq.*), North Carolina False Claims Act (N.C. Gen. Stat. §§ 1-605 *et seq.*), Oklahoma Medicaid False Claims Act (Okla. Stat. tit. 63, §§ 5053 *et seq.*), Rhode Island False Claims Act (R.I. Gen. Laws §§ 9-1.1-1 *et seq.*), Tennessee Medicaid False Claims Act (Tenn. Code Ann. §§ 71-5-181 *et seq.*), Texas Medicaid Fraud Prevention Act (Tex. Hum. Res. Code §§ 36.001 *et seq.*), Virginia Fraud Against Taxpayers Act (Va. Code Ann. §§ 8.01-216.1 *et seq.*), Washington Medicaid Fraud False Claims Act (Wash. Rev. Code §§ 74.66 *et seq.*), and Wisconsin False Claims for Medical Assistance Act (Wis. Stat. §§ 20.931 *et seq.*) (collectively the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the federal False Claims Act and the State False Claims Acts;

(b) Community Hospital of the Monterey Peninsula for violations of the federal False Claims Act and California False Claims Act to recover all damages, civil penalties and all other recoveries provided thereunder; and

(c) Yale-New Haven Hospital, Inc. for violations of the federal False Claims Act and the Connecticut False Claims Act to recover all damages, civil penalties and all other recoveries provided thereunder.

## I.
## SUMMARY OF THE ACTION

2. This False Claims Act lawsuit arises from a nationwide scheme to defraud Medicare and Medicaid engineered by Executive Health Resources, Inc. ("EHR" or the "Company"), by far the largest so-called "physician-advisor" company in the nation, with approximately 2,400 hospitals in 50 states using its services. Since at least 2006, EHR has been improperly "certifying" emergent and elective outpatient cases for hospital inpatient admission and payment. Hospitals and physicians then rely on these certifications to submit claims for payment to the government. As a result of the different methodologies for inpatient reimbursement under Medicare Part A and outpatient reimbursement under Medicare Part B, hospitals typically receive a significantly higher payment – often up to $5,000 more – if a patient is designated as an inpatient rather than as an outpatient receiving observation services. Defendant EHR has fraudulently exploited this difference in reimbursement methodology by devising a case review process that violates Medicare and Medicaid regulatory requirements, and which falsely "certifies" thousands upon thousands of cases as qualifying for inpatient admission when these cases could be safely and effectively treated by utilizing outpatient "observation" care. EHR's false certifications thus render its client hospitals' as well as the treating physicians' claims for payment on an inpatient basis entirely false and misleading. By knowingly supplying hospitals with false inpatient certifications that it knows causes the hospitals to present false or fraudulent inpatient claims for payment to Medicare and Medicaid, EHR has violated 31 U.S.C. § 3729(a)(1)(A). In addition, by knowingly making false records or statements (*i.e.*, the inpatient certifications) material to the false or fraudulent inpatient claims that hospitals submit to Medicare and Medicaid, EHR has violated 31 U.S.C. § 3729(a)(1)(B).

3. EHR clients, Community Hospital of the Monterey Peninsula and Yale-New Haven Hospital, knew or recklessly disregarded that EHR's inpatient certifications do not comply with Medicare and Medicaid payment requirements. Both of these hospitals, nevertheless, relied upon and adopted EHR's fraudulent inpatient certifications to submit false inpatient claims to Medicare and Medicaid and thereby receive higher payments in violation of the federal False Claims Act as well as the California and Connecticut false claims statutes.

4. On August 4, 2010, EHR was acquired by OptumInsight, Inc. (formerly known as Ingenix) – a subsidiary of the largest provider of Medicare Advantage insurance, United HealthCare Services, Inc., which is part of UnitedHealth Group Incorporated's family of health care businesses – where the Company has continued providing hospitals false inpatient certifications. In fact, OptumInsight, Inc. and another UnitedHealth Group business, Optum, Inc., control EHR and have boosted EHR's and the UnitedHealth Group family's fortunes by selling EHR's fraudulent inpatient review and certification services to their vast stable of hospital clients.

5. This carefully constructed fraud, which underlies not only EHR's success, but its very viability as a business enterprise, has resulted in enormous damage, all at the expense of the American taxpayer. Billions of dollars in falsely inflated reimbursement amounts have already been paid out by Medicare and Medicaid to hospitals and physicians, and the fraud continues today. Defendant EHR, meanwhile, enjoys meteoric growth in market share and revenues, likely generating annual profits in excess of $100 million for EHR and its UnitedHealth Group owners.

## II.
## JURISDICTION AND VENUE

6. Jurisdiction is founded upon the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, specifically 31 U.S.C. §§ 3732(a) & (b) and also 28 U.S.C. §§ 1331 & 1345.

7. Venue in the Eastern District of Pennsylvania is appropriate under 31 U.S.C. § 3732(a) and sufficient contacts exist for jurisdiction in that many of the acts complained of took place in this district and Executive Health Resources's principal place of business is located in the district.

## III.
## PARTIES

8. The United States is a plaintiff to this action. The United States brings this action on behalf of the Department of Health and Human Services and the Centers for Medicare & Medicaid Services (CMS), which administers the Medicare and Medicaid Programs. Medicare and Medicaid are sometimes collectively referred to herein as "Government Payers."

9. The State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Washington, and the State of Wisconsin are plaintiffs to this action. The Plaintiff States bring this action on behalf of their respective Medicaid programs and agencies as well as their respective State interests.

10. Relator Jesse Polansky, M.D., M.P.H., is a citizen of the United States and a resident of Baltimore, Maryland. Dr. Polansky is a licensed physician with broad-based Medicare, Medicaid, and commercial health insurance experience in evidence based medicine and informatics. From 2003 until 2011, Dr. Polansky held leadership positions within CMS.

Most recently, he served as the senior Medical Officer of CMS's Provider Compliance Group where he led medical review operations of the Medicare Administrative Contractors ("MACs"), Recovery Audit Contractors ("RACs") and the Comprehensive Error Rate Testing ("CERT") program. Each of these national programs addresses provider compliance with Medicare's clinical and operational policies, including those pertaining to hospital coverage and payment policy. Prior to holding that position, Dr. Polansky served as the senior Medical Officer of the Program Integrity Group, providing leadership to CMS's fraud, waste, and abuse programs as well as its contractors and law enforcement partners. Dr. Polansky has also served in a number of leadership positions within the private health care sector.

11. Dr. Polansky received his Bachelor's degree in chemistry from Wesleyan University and his medical degree from Mount Sinai School of Medicine. He was awarded a Master of Public Health, Division of Health Policy and Management from the Columbia University School of Public Health. On or about December 14, 2011, Dr. Polansky began advising senior management at defendant EHR regarding regulatory affairs, business development, new product development, and professional services. On or about February 13th of the following year, after raising Medicare compliance related issues regarding EHR's policies and procedures surrounding Medicare payments for inpatient versus outpatient services with EHR management, Dr. Polansky ceased working with EHR.

12. The allegations in this Complaint are grounded in information Dr. Polansky discovered during the course of his work with EHR and, in particular, during discussions Dr. Polansky had with management personnel, his attendance at EHR training programs, and his review of documents EHR provided to him.

13. Defendant Executive Health Resources Inc. is a physician advisor company whose headquarters are located in Newtown Square, Pennsylvania. The Company provides payment certification services to hospitals and health care systems for Medicare and Medicaid patients and private commercial health plan patients, pursuant to which cases are certified by EHR for billing purposes as either inpatient or outpatient. These certification services are performed in the context of patients arriving at a hospital and entering the emergency department or as direct admissions as well as patients undergoing outpatient surgery. Additionally, EHR handles appeals from those instances in which Medicare or Medicaid denies coverage of patients who were admitted and billed as an inpatient. EHR, a Pennsylvania corporation, was founded in 1997 by Dr. Robert Corrato, who remains the Company's Strategic Advisor. The Company is a subsidiary of OptumInsight, which is itself a subsidiary of UnitedHealth Group Incorporated.

14. Defendant UnitedHealth Group Incorporated ("UHG") is a Minnesota corporation with its principal place of business located at UnitedHealth Group Center, 9900 Bren Road East, Minnetonka, Minnesota 55343. UHG is a publicly-owned corporation whose common stock trades on the New York Stock Exchange. UHG supplies a broad range of health care services, such as health care benefits to individuals and employers, retail pharmacy network claims processing and assistance to hospitals, to improve clinical performance, financial performance and regulatory compliance. According to UHG's Annual Report filed with the Securities and Exchange Commission on Form 10-K, UHG had revenues of $101.8 billion in the year ended December 31, 2011. UHG owns and controls defendants United HealthCare Services, Inc., Optum, Inc., OptumInsight Holdings, LLC, OptumInsight, Inc. and EHR.

15. Defendant United HealthCare Services, Inc. ("UHCS") is a Minnesota corporation that shares its headquarters with UHG. UHCS is a subsidiary of UHG. Together

with UHG, UHCS owns and controls defendants Optum, Inc., OptumInsight Holdings, LLC, OptumInsight, Inc., and EHR.

16. Defendant Optum, Inc. ("Optum"), f/k/a RIO Holdings, Inc.[1], is a Delaware corporation that shares its headquarters with UHG and UHCS. Optum is a subsidiary of UHCS and is one of the main business platforms of UHG. Optum is organized into three segments, one of which is OptumInsight. Together with UHG and UHCS, Optum owns and controls defendants OptumInsight Holdings, LLC, OptumInsight, Inc., and EHR.

17. Defendant OptumInsight Holdings, LLC ("OptumInsight Holdings"), f/k/a Ingenix Holdings, LLC, is a Delaware limited liability company. OptumInsight Holdings is a subsidiary of Optum. Together with UHG, UHCS, and Optum, OptumInsight Holdings owns and controls OptumInsight, Inc. and EHR.

18. Defendant OptumInsight, Inc. ("OptumInsight"), f/k/a Ingenix, Inc., is a Delaware corporation with its principal place of business located at 13625 Technology Drive, Eden Prairie, Minnesota 55344. OptumInsight is a health information, technology, services and consulting company providing software and information products, advisory consulting services, and business process outsourcing to participants in the health care industry. OptumInsight is a subsidiary of OptumInsight Holdings. Together with UHG, UHCS, Optum, and OptumInsight Holdings, OptumInsight owns and controls EHR.

19. UHG, UHCS, Optum, OptumInsight Holdings, and OptumInsight are collectively referred to herein as the "UHG Defendants."

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[1] In 2011, UHG caused Optum, OptumInsight Holdings, and OptumInsight to change their names as part of a realignment that took effect at the beginning of 2011.

20. At all relevant times, the management, supervision, control, reporting, and financial exchanges by and between EHR, UHG, UHCS, Optum, OptumInsight Holdings, and OptumInsight have been so inextricably intertwined that in effect they have operated as one single entity.

21. Defendant Community Hospital of the Monterey Peninsula ("CHOMP") is a California privately-owned, non-profit corporation located at 23625 W.R. Holman Highway, Monterey, California 93940. CHOMP operates a 208-bed hospital where it provides among other health care services, emergency services and outpatient medical services. CHOMP is owned by Community Hospital Foundation.

22. Defendant Yale-New Haven Hospital, Inc. ("YNHH") is a Connecticut privately-owned, non-profit corporation located at 20 York Street, New Haven, Connecticut 06510. YNHH operates a 944-bed tertiary referral center that includes the 201-bed Yale-New Haven Children's Hospital and the 76-bed Yale-New Haven Psychiatric Hospital. YNHH is the primary teaching hospital for Yale University School of Medicine and thus its staff includes 471 supervised resident physicians. YNHH is owned by YNH Network Corporation, which is owned by Yale-New Haven Health Services Corporation.

## IV.
## STATUTORY AND REGULATORY FRAMEWORK

### A. The Federal False Claims Act (FCA) (31 U.S.C. §§ 3729 *et seq.*)

23. On May 20, 2009, Congress enacted the Fraud Enforcement Recovery Act (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the FCA and re-designated § 3729(a)(1) as § 3729(a)(1)(A), § 3729(a)(2) as § 3729(a)(1)(B), and § 3729(b) as §§ 3729(b)(1)(A) & (B).

24. The pre-FERA version of the FCA imposed liability on:

> [A]ny person who—
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

31 U.S.C. § 3729(a)(1)-(2). The FCA, as FERA has amended it, now imposes liability on:

> [A]ny person who—
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

31 U.S.C. § 3729(a)(1)(A)-(B).

25. The term "knowingly" means "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b) (pre-FERA); 31 U.S.C. § 3729(b)(1)(A) (post-FERA). Proof of specific intent to defraud is not required. *See* 31 U.S.C. § 3729(b) (pre-FERA); 31 U.S.C. § 3729(b)(1)(B) (post-FERA).

26. FERA provides that amendments to the FCA take effect upon enactment except for the amendment to the old § 3729(a)(2), which "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act ... that are pending on or after that date." FERA § 4(f)(1), 123 Stat. at 1625.

27. Here, EHR's alleged FCA violations span from at least January 2006 forward, CHOMP's alleged FCA violations span from 2007 forward, and YNHH's alleged FCA

violations span from at least 2008 forward, accordingly, the pre-FERA FCA §§ 3729(a)(1) and 3729(b) apply to all alleged FCA violations that occurred before May 20, 2009 and the amended versions of those Sections (§ 3729(a)(1)(A) and §§ 3729(b)(1)(A) & (B)) apply to all alleged FCA violations that occurred on or after May 20, 2009. In addition, pre-FERA § 3729(a)(2) applies to all claims no longer pending as of June 7, 2008, and the amended version (§ 3729(a)(1)(B)) applies to all alleged false claims pending on or after June 7, 2008. All alleged FCA claims against the UHG Defendants relate to violations that occurred from August 4, 2010 to the present, therefore, the amended version of the FCA applies to all claims against the UHG Defendants.

28. The pre-FERA version of the FCA defined the term "claim" as meaning:

> [A]ny request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(c). Post-FERA, the FCA now defines the term ''claim'' as:

> [A]ny request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
>
> (i) is presented to an officer, employee, or agent of the United States; or
>
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
>
> (I) provides or has provided any portion of the money or property requested or demanded; or
>
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

* * *

31 U.S.C. § 3729(b)(2).

29. Under 31 U.S.C. § 3729(b)(4) (post-FERA), the term ''material'' means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

30. Each of the Plaintiff States has individually enacted false claims statues that contain provisions similar to those quoted above. Dr. Polansky asserts claims under the State False Claims Acts to recover for the Plaintiff States the amounts they paid to hospitals as a result of the false claims presented to the States' Medicaid Programs.

31. Where one or more persons commit a fraud upon the government in violation of the Federal False Claims Act and State False Claims Acts, each is jointly and severally liable for the treble damages and statutory penalty. *See, e.g., Mortgages, Inc. v. U.S. Dist. Ct. for the Dist. of Nev.*, 934 F.2d 209, 212 (9th Cir. 1991); Cal. Gov. Code § 12651(c); Conn. Gen. Stat. § 17b-301b(b).

**B. The Medicare & Medicaid Programs**

32. The Medicare Program, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395iii, is a federal health insurance program that pays for covered medical care provided to eligible aged and disabled persons. Two major parts of Medicare – Parts A & B – pay for medical items and services on a "fee-for-service" basis. Medicare Part A authorizes payments for covered hospital inpatient services and other institutional care, including skilled nursing facility and home health care services. *See* 42 U.S.C. §§ 1395c, 1395d, 1395i. Medicare Part B establishes a voluntary supplemental insurance program that pays for various medical and

other health services and supplies, including physician services, physical, occupational, and speech therapy services and hospital outpatient services. *See id.* §§ 1395k, 1395m, 1395x.

33. Medicaid is a government health insurance program for the poor (the "Medicaid Program") that is jointly funded by the federal and state governments. *See* 42 U.S.C. §§ 1396 *et seq.* Each State administers its own Medicaid program. However, each State program is also governed by federal statutes, regulations and guidelines. The federal portion of each State's Medicaid payment – the Federal Medical Assistance Percentage – is based on that State's per capita income compared to the national average. During the relevant time period, the Federal Medical Assistance Percentage was between approximately 50% and 80%.

34. Participants in the Medicare and Medicaid programs have a duty to familiarize themselves with the legal requirements for cost reimbursement, including the requirements applicable to hospital status. *See Heckler v. Cmty. Health Services,* 467 U.S. 61, 64 (1984); *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001); *Massachusetts v. Mylan Labs.*, 608 F.2d 127, 154 (D. Mass. 2008).

35. Medical necessity is a fundamental requirement for Medicare and Medicaid coverage. Medicare and Medicaid do not cover any expenses incurred for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury …." 42 U.S.C. § 1395y(a)(1)(A); Medicare Benefit Policy Manual ("MBPM"), ch. 16 § 20 (Rev. 1, 10-01-03).

36. To be covered by Medicare and Medicaid, services must not only be reasonable and necessary, they must also be provided, billed and paid in the most economical manner. This economical manner requirement is set forth in multiple federal statutes and CMS regulations prescribing the responsibilities and obligations of health care practitioners, providers of health care services (including hospitals), and contractors who review claims for payment.

37. Federal law requires practitioners and providers to assure that services are provided "**economically** and only when, and to the extent, medically necessary" (emphasis added):

> (1) will be provided economically and only when, and to the extent, medically necessary;
>
> (2) will be of a quality which meets professionally recognized standards of health care; and
>
> (3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities.

42 U.S.C. § 1320c-5(a).

38. CMS regulations similarly require practitioners who order institutional services to provide such services in an economical manner:

> It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are:
>
> (a) Provided economically and only when, and to the extent, medically necessary;
>
> * * *

42 C.F.R. § 1004.10; accord Quality Improvement Organization Manual ("QIO Manual"), ch. 9 § 9000 (Rev. 12, 10-03-03).

39. Medicare review and payment contractors who review institutional claims (*i.e.*, claims submitted by providers), including, but not limited to, fiscal intermediaries and carriers (FIs) and Medicare Administrative Contractors (MACs), like their predecessor Quality Improvement Organizations (QIOs), are required to check whether services were provided,

billed, and paid in the most economical manner.[2] Congress requires Medicare to employ FIs and MACs to make payment decisions concerning health care services provided to beneficiaries through the application of statutory coverage exclusions. *See* 42 U.S.C. §§ 1395y(g), 1320c-2, & 1320c-3(a)(2). This system of review was designed to "promot[e] the effective, efficient, and economical delivery of health care services ...." 42 U.S.C. § 1395y(g). Thus, federal law requires FIs and MACs to consider, in addition to other requirements, whether the services, including hospital inpatient and hospital outpatient services, are provided, billed, and paid in the most economical manner:

> The organization shall review some or all of the professional activities in the area ... of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made ... for the purpose of determining whether—
>
> (A) such services and items are or were reasonable and medically necessary and whether such services and items are not allowable under subsection (a)(1) or (a)(9) of section 1395y of this title;
>
> * * *
>
> (C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, **be effectively provided more economically on an outpatient basis** or in an inpatient health care facility of a different type.

42 U.S.C. § 1320c-3(a)(1) (emphasis added).

40. Consistent with Congress's stated intent, CMS has explained that one of the primary purposes of QIO reviews is to "[p]rotect the integrity of the Medicare Trust Fund **by**

---

[2] In 2008, responsibility for non quality-related medical review of claims was transferred from the QIOs to FIs and MACs. FIs and MACs subsequently became responsible for reviewing reimbursement claims submitted to CMS through the application of the same policies and requirements Congress and CMS originally assigned to QIOs. Accordingly, although the statutes and regulations reference QIOs, they apply with equal force to FIs and MACs.

**ensuring that Medicare pays only** for services and goods that are reasonable and medically necessary and that are provided in the most appropriate setting." QIO Manual, Ch. 1 § 1005 (Rev. 16, 06-30-06) (emphasis added). And, in accordance with Congress's mandate, CMS instructs QIOs (and now FIs and MACs) that, in deciding whether Medicare will pay for hospital inpatient services, they must determine whether the services should have been provided, billed, and paid as less expensive hospital outpatient services or in an inpatient health facility of a different type:

> Section 1154(a)(2) of the [SSA] requires you to determine, based on your review of services furnished by health care practitioners and providers, whether payment should be made by Medicare. This requirement is fulfilled through a variety of activities, all of which are designed to reduce the percentage of Medicare dollars paid improperly for:
>
> - Medically unnecessary or unreasonable care (*see* §1154(a)(1)(A));
> - Inpatient care that could have been provided in a more economical setting (*see* §1154(a)(1)(C));
> - Hospital actions that circumvent Medicare payment rules (*see* §1886(f)(2));
>
> * * *

QIO Manual, ch. 11 § 11000 (Rev. 8, 08-29-03) (emphasis added).

41. Of particular relevance here, Medicare regulations require QIOs (and now FIs and MACs) to make the following economic determinations in deciding whether Medicare will pay for a service billed as an hospital inpatient service:

> Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, **be effectively furnished more economically on an outpatient basis** or in an inpatient health care facility of a different type.

42 C.F.R. § 476.71(a)(3) & (b) (emphasis added).

42. Likewise, in assessing the need for and appropriateness of an hospital inpatient admission, CMS requires FIs and MACs to consider, among other criteria, "the necessity for

facility admission and continued stay" and whether "a lower and less costly level of care would [have been] equally effective." 42 C.F.R. § 476.100(b).

43. These authorities demonstrate that Congress and CMS view the requirement of providing, billing, and payment for care in the most economical manner as mandatory. Moreover, these authorities also make clear that, in making Medicare/Medicaid payment decisions, FIs and MACs must – separate and apart from reviewing medical necessity – determine whether the services were provided and billed in the most economical manner.

44. And so, EHR should only be certifying that services meet Medicare and Medicaid payment requirements for inpatient status when hospital care is reasonable and necessary and the same treatment cannot be provided and billed more economically in hospital outpatient status.

45. Finally, to obtain reimbursement for services provided to a Medicare or Medicaid beneficiary, hospitals submit Form CMS-1450 (UB-04). In submitting Form 1450, the provider expressly certifies, among other things, that:

- "the billing information as shown on the face hereof is true, accurate and complete"; and
- "the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts."

### C. The Amount Hospitals Are Reimbursed By Medicare And Medicaid For Medical Services Is Materially Impacted By Whether The Patient Is Classified As *Inpatient* Or *Outpatient* Status

46. Both "inpatient" and "outpatient" are assigned hospital statuses that affect how much government healthcare programs and patients will pay for hospital services as well as the methodology used to arrive at the payment amount. As discussed herein, Medicare's and Medicaid's laws, regulations, and manuals determine the appropriate status.

**1. The difference between *inpatient* and *outpatient observation services***

47. An ***inpatient***, for purposes of Medicare, is:

> [A] person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as an inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.

MBPM, ch. 1 § 10; *see also Landers v. Leavitt*, 545 F.3d 98, 111 (2d Cir. 2009).

48. With regard to the determination of whether a patient should be admitted as an inpatient, the Medicare Benefit Policy Manual makes clear that (1) whether the physician expects the patient to remain in the hospital for 24 hours or more should be used as a benchmark, and (2) this is a "complex medical judgment" that requires consideration of a range of factors:

> … Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:
>
> - The severity of the signs and symptoms exhibited by the patient;
> - The medical predictability of something adverse happening to the patient;
> - The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
> - The availability of diagnostic procedures at the time when and at the location where the patient presents.
>
> Admissions of particular patients are not covered or noncovered solely on the basis of the length of time the patient actually spends in the hospital. In certain specific situations coverage of services on an inpatient or outpatient basis is

determined by the following rules:

> Minor Surgery or Other Treatment - When patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered outpatients for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.

MBPM, ch. 1 § 10 (Rev. 1, 10-01-03).

49. In the wake of persistently large improper payment rates for short-stay hospital inpatient claims and extended outpatient observation stay claims, CMS recently issued 42 C.F.R. § 412.3(e)(1). This rule reinforced the longstanding importance of the 24-hour benchmark in deciding whether an inpatient admission was reasonable and necessary under Medicare, while also clarifying that methodology for calculating the 24-hour benchmark. The CMS "two midnight rule" provides in relevant part:

> **[W]hen a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n) of this chapter, a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A**, regardless of the hour that the patient came to the hospital or whether the patient used a bed. Surgical procedures, diagnostic tests, and other treatment are generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights. …

42 C.F.R. § 412.3(e)(1) (emphasis added).

50. In CMS's commentary to the "two midnight rule," CMS reiterated its past guidance regarding inpatient admission decisions. In so doing, it:

(a) rejected references to "level of care" in making such decisions given the longstanding requirement of a "time-based admission framework to effectuate appropriate inpatient hospital admission decisions" 78 Fed. Reg. 50,945 (CMS Aug. 19, 2013) (citing the

recent findings of the Office of Inspector General (OIG), Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI-02-12-00040, 1812 July 2013); and

(b) instructed that Medicare patients should be placed in observation when a determination of expected length of stay is difficult. Specifically, CMS stated:

> [W]hen it [is] difficult to make a reasonable prediction, the physician should not admit the beneficiary but should place the beneficiary in observation as an outpatient. As new information becomes available, the physician must then reassess the beneficiary to determine if discharge is possible or if it is evident that an inpatient stay is required. We believe that this principle still applies and have reiterated this in the final rule.

*Id.*

51. The Medicare Benefit Policy Manual further provides that "[t]he physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient." MBPM, ch. 1 § 10 (Rev. 1, 10-01-03).

52. It is a condition to participation in the Medicare program that a hospital's governing body ensures that "[p]atients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital." 42 C.F.R. § 482.12(c)(2).

53. To reinforce this requirement, CMS issued 42 C.F.R. § 412.3:

> The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is knowledgeable about the patient's hospital course, medical plan of care, and current condition. The practitioner may not delegate the decision (order) to another individual who is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.

42 C.F.R. § 412.3 (2013).

54. Medicare, as a condition of payment, requires a physician order to justify inpatient status:

> (a) *Content of certification and recertification.* Certification begins with the order for inpatient admission. Medicare Part A pays for inpatient hospital services (other than inpatient psychiatric facility services) only if a physician certifies and recertifies the following:
>
> (1) That the services were provided in accordance with § 412.3 of this chapter.
>
> (2) The reasons for either—
>
> (i) Hospitalization of the patient for inpatient medical treatment or medically required inpatient diagnostic study; or
>
> ***
>
> (3) The estimated time the patient will need to remain in the hospital.
>
> ***
>
> (b) *Timing of certification.* For all hospital inpatient admissions, the certification must be completed, signed, and documented in the medical record prior to discharge. …
>
> ***
>
> (d) *Signatures.*—(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section, certifications and recertifications must be signed by the physician responsible for the case, or by another physician who has knowledge of the case and who is authorized to do so by the responsible physician or by the hospital's medical staff.

42 C.F.R. § 424.13 (2013).

55. CMS reiterated and codified in 42 C.F.R. § 412.46(b) the longstanding requirement that medical judgment and documentation must support the physician's order and certification, as prescribed by CMS Ruling 93-1:

> No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of this chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order and certification will be evaluated in the context of the evidence in the medical record.

42 C.F.R. § 412.46(b) (2013).

56. In accordance with Medicare program requirements, fiscal intermediaries, Medicare Administrative Contractors, and other contractors review medical records for inpatient claims to confirm that inpatient hospital care was reasonable and necessary and provided in the most economical manner. *See* Medicare Program Integrity Manual, ch. 6.5.2 (Rev. 264, 08-07-08). Inpatient services are deemed to be reasonable and necessary only where the patient's signs and symptoms were so severe that the services could not be safely and effectively provided on an hospital outpatient basis:

> Review of the medical record must indicate that inpatient hospital care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the beneficiary at any time during the stay. The beneficiary must demonstrate signs or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively **only** on an inpatient basis.
>
> * * *
>
> Inpatient care rather than outpatient care is required **only** if the beneficiary's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting....

*Id.* (emphasis added).

57. In the context of Medicare, ***outpatient hospital observation*** care ("observation" or "outpatient observation") are services hospitals furnish on their premises, including use of a bed and at least periodic monitoring by nurses or other staff, that are reasonable and necessary to evaluate an outpatient's condition or determine the need for possible admission as an inpatient:

> Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

MBPM, ch. 6 § 20.6 (Rev. 107, 05-22-09); Medicare Claims Processing Manual, ch. 4 § 290.1 (Rev. 1760, 06-23-09) & ch. 12 § 30.6.8 (Rev. 2282, 08-26-11).

58. The purpose of observation is to determine whether further treatment or inpatient admission is required. *See id.* Accordingly, a patient who receives hospital observation care is either discharged because their condition has improved, or admitted as an inpatient. *See id.*

59. Additionally, to be covered by Medicare, observation services must be "provided by the order of a physician or another individual authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient tests." *Id.*

60. Like inpatient hospital care, outpatient hospital observation services must be reasonable and necessary to be covered by Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A). In only rare and exceptional cases do reasonable and necessary outpatient observation services span beyond 48 hours. *See* MBPM, ch.6 § 20.6. Rather, the decision whether to discharge the patient or admit them inpatient typically can be made in less than 48 hours, and usually less than 24 hours. *See id.*

61. Most, if not all, state Medicaid programs observe the same or comparable distinctions between hospital inpatient and outpatient hospital services as Medicare.

62. And, as is the case with Medicare, the various state Medicaid programs will only cover services provided to beneficiaries where such services are reasonable and necessary and provided, billed, and paid in the most economical manner. *See* 42 U.S.C. § 1320c-5(a); *see also, e.g.*, 130 Mass. Code Regs. 415.414(B)(2); Tex. Medicaid Provider Proc. Manual, Inpatient & Outpatient Hosp. Services Handbook § 3.1 (2012); N.C. Medicaid Program, Div. of Med. Assistance, Acute Inpatient Hosp. Services, Clinical Coverage Policy No: 2A-1 § 3; Mich. Medicaid State Plan, Suppl. to Attachment 3.1-A.

**2. Hospitals generally receive higher reimbursements from Medicare and Medicaid for care provided to a patient classified as *inpatient* than for care provided to a patient classified as *outpatient***

63. The amount Medicare and Medicaid reimburse hospitals for a medical service turns on whether the patient is classified as *inpatient* or *outpatient*.

64. Hospital ***inpatient*** services are covered under Medicare Part A (Hospital Insurance). Under Medicare Part A, hospitals are reimbursed for an inpatient stay based on the patient's diagnosis, which is categorized by its Diagnosis Related Group ("DRG"). In most cases, the length of stay is not a factor. Thus, the hospital receives the same reimbursement amount regardless of how many days the patient remains in the hospital.

65. Services that are provided to a patient who is in ***outpatient*** hospital status, including, but not limited, to observation services, are covered under Medicare Part B (Medical Insurance). In calculating payment rates for services performed to patients assigned to outpatient status, Medicare utilizes the Outpatient Prospective Payment System ("OPPS"). All outpatient services paid under the OPPS are classified into groups called Ambulatory Payment Classifications ("APC"). Hospitals may be paid for more than one APC for a patient visit. Often, the payment for observation services is bundled with other services.

66. Medicare generally pays about $4,500-$5,000 more for inpatient services under the DRG system than it does when the same services are provided to a patient classified as outpatient observation and the APC classifications apply. Moreover, the disparity between DRG and APC payments grows especially large when short hospital stays, including surgical cases, are involved. Consequently, there is a strong financial incentive for hospitals to formally admit patients as inpatients even though they can be safely and effectively as well as more economically treated as outpatients.

67. Most, if not all, state Medicaid programs apply a reimbursement methodology comparable to Medicare's for inpatient and outpatient hospital observation services. Thus, for instance, when EHR performed [redacted]

68. Physician billing for hospital services is required to conform to hospital status. In general, physicians get paid more for providing services to patients who are assigned to inpatient status than those assigned to outpatient status.

69. In contrast to traditional Fee-For-Service Medicare and Medicaid, Medicare Advantage plans are not required to pay hospitals using DRGs (*i.e.*, a fixed payment irrespective of the number of days the beneficiary stays in inpatient status). Some of these plans, including plans administered by UHCS, pay hospitals on a per diem basis. Under this payment method, payment for a patient classified as a hospital inpatient can be different from the payment for a patient classified as outpatient.

70. Finally, the beneficiary has no financial liability when the government recovers dollars for improper payments due to provider fraud, waste, or abuse. This would apply when recoveries are made for incorrect hospital status determinations due to the fraud alleged herein.

**D. The Attending Physician's Initial Inpatient/Outpatient Decision And The Hospital's Review**

71. As described in paragraphs 51 to 54 above, only a licensed physician can legally admit a patient to a hospital. Hence, the attending physician generally makes the initial judgment as to whether it is most economical and reasonable and necessary for a patient to be admitted as an inpatient rather than be treated on an outpatient basis.

72. Typically, and consistent with 42 C.F.R. § 482.30, as a first level review to determine hospital status, hospitals employ a utilization review ("UR") committee that applies physician-approved, industry-standard, hospital utilization management criteria ("UM Criteria"), such as MillimanCare Guidelines or InterQual Criteria, to determine which status is most economical and reasonable and necessary, namely (1) inpatient, (2) outpatient status with observation care, or (3) discharge from the hospital shortly after receiving treatment and evaluation services in the emergency department. Hospitals as necessary re-apply these screening tools as new clinical diagnostic and therapeutic information about a patient becomes available. 42 C.F.R. § 482.30 specifically requires:

> The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.
>
> ***
>
> (c) *Standard: Scope and frequency of review.*
>
> (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—
>
> (i) Admissions to the institution;
>
> (ii) The duration of stays; …
>
> (2) Review of admissions may be performed before, at, or after hospital admission.

73. Pursuant to 42 C.F.R. § 482.30, when an attending physician's order is for inpatient admission, a UR committee is restricted from unilaterally determining that the inpatient admission is not reasonable and necessary without at least providing the attending physician an opportunity to be heard. In contrast, however, when a UR committee disagrees with an attending physician's order for outpatient observation care, the UR committee is not required under 42 C.F.R. § 482.30 to review with the attending physician its determination that inpatient admission

is reasonable and necessary and provided in the most economical manner. Hence, the UR committee can unilaterally change patients' status from outpatient observation to inpatient.

74. Frequently, when a patient does not qualify for inpatient status under the UM Criteria, hospitals utilize a "physician advisor" conduct a second review. *See* TMF Health Quality Inst., the Quality Improvement Org. Support Ctr. for the Hosp. Payment Monitoring Program, Hosp. Payment Monitoring Program Compliance Workbook at 38 (2008).

75. Some hospitals employ an on-site physician advisor, while others engage a physician advisor firm, such as EHR, to perform second level reviews off-site.

## E. The Government Has Stepped-Up Its Scrutiny Of Hospitals' Practices Concerning The Classification Of Medicare And Medicaid Beneficiaries As Inpatient Rather Than Outpatient Status

76. The amount of taxpayer dollars at stake in ensuring that hospital payments are compliant with Medicare and Medicaid law, regulations and guidance easily measures in the billions. According to EHR, the average increase in per patient Medicare payment on an inpatient basis versus an outpatient basis is nearly $5,000. In 2009 alone, Medicare spent $114 billion on fee-for-service inpatient care for roughly 10 million Medicare inpatient admissions and another $34 billion on outpatient care for 147 million outpatient services. *See* MedPac, *Report to the Congress: Medicare Payment Policy*, ch. 3 (2011).

77. In recent years the federal government has been subjecting the propriety of hospital inpatient admissions and payments to heightened scrutiny and has taken significant steps toward preventing hospitals from billing Medicare for inpatient stays that should have been treated as outpatient observation cases. Medicare's Comprehensive Error Rate Testing Program has identified short stay inpatient admissions as a leading source of improper claims accounting for billions of dollars of improper Medicare payments. It is a priority review area for Medicare,

OIG, and the DOJ. The OIG has targeted short stay hospital admissions through audits, and one-day hospital stays have been the subject of Medicare's Program for Evaluating Payment Patterns Electronic Reports ("PEPPER reports").

78. The United States also implemented the Recovery Audit Contractors ("RAC") program on a permanent basis in or after 2008. Under this program, Medicare takes back from the RAC audited hospital each overpayment the RAC detects, and the RAC receives a percentage thereof. A primary area of focus for RACs has been improper payments for short stay hospital admissions. RAC reviews have revealed significant evidence of improper payments for inpatient admissions when it is not reasonable and necessary and the care could have been provided more economically in hospital outpatient status. Medical necessity denials represented 40% of the recovery dollars in the three-state (New York, California & Florida) RAC pilot program through March 2008, and most of those were short stay inpatient denials.

79. In addition, the federal government is utilizing Medicare Administrative Contractors ("MACs") to combat unnecessary hospital admissions and payments by having them review whether inpatient admissions were reasonable and necessary and whether the care could have been provided more economically in hospital outpatient status.

80. Moreover, in 2004, CMS began allowing hospital UR committees to retroactively change patients' status from inpatient to outpatient if the patient is still in the hospital and the treating physician concurs with the change. Another mechanism the federal government has successfully employed to curtail inappropriate inpatient admissions is bringing actions against hospitals and other health care providers for violating the federal False Claims Act.

## V.
## FACTUAL ALLEGATIONS

### A. EHR Background

81. Because the government health care programs pay hospitals more for services provided to patients who are inpatient status than for the same services provided to patients who are outpatient status, when a case does not meet the UM Criteria for inpatient status, many hospitals seek out an alternative basis to assign inpatient status to the case through a second level review.

82. EHR, which was founded in 1997 has developed a core business of providing hospitals a means of increasing their revenue by performing second level inpatient status review services on a concurrent basis (*i.e.*, while the patient is in the hospital and before a final decision as to whether a patient will be admitted has been made). This core physician advisor business dates back to at least to 2003. Typically, hospitals retain EHR to perform a second level review of all cases where the attending physician's initial status determination fails the UM Criteria for inpatient status. According to its website, EHR has "successfully performed more than 10 million medical necessity reviews" on behalf of hospitals. EHR Corporate Overview, http://www.ehrdocs.com/aboutehr_corporateoverview.php (last viewed Mar. 24, 2014). Certain hospitals also retain EHR to represent it in appealing inpatient claims that were denied. EHR advertises on its website that it has "successfully identified and reversed thousands of inappropriate medical necessity denials, concurrently and retrospectively, at all levels of appeal." *Id.*

83. EHR's main mantra is that it creates greater "revenue integrity" for client hospitals. What EHR actually means by this *Orwellian* turn of phrase is that greater numbers of

patients will be billed as inpatient status if EHR performs certification services for the hospital, thereby generating a revenue windfall for the hospital.

84. Throughout the relevant time period, EHR has engaged in an extremely aggressive and sophisticated marketing program centered on three main themes to induce over 2,000 U.S. hospitals to retain EHR to perform inpatient medical necessity reviews:

(1) EHR is the leading expert on Medicare rules and regulations governing the inpatient vs. outpatient hospital status decision;

(2) Attending physicians do not understand the Medicare rules and regulations and are too busy with patients to focus on determining the proper care setting; and

(3) Reliance on EHR will shield the hospitals from liability.

**1. EHR holds itself out as an "expert" on inpatient vs. outpatient status**

85. In presentations to hospitals, EHR promotes itself as "the national expert in medical necessity" and claims that:

> EHR is the industry pioneer and leading provider of outsourced Medical Necessity Compliance Solutions utilizing specially-trained physicians, clinical and regulatory research, specialized technology, quality assurance processes, unique expertise and experience with the ALJs/DOJ/OIG, and the industry's largest database of validated medical necessity compliance reviews.

Similarly, it describes itself as having, "[u]nique clinical regulatory and legal expertise in CMS compliance and the DOJ/OIG." On its website, EHR refers to its physician advisors as "The Medical Necessity Authority in the healthcare industry." EHR Corporate Overview, http://www.ehrdocs.com/aboutehr_corporateoverview.php (last viewed Mar. 24, 2014).

86. EHR also claims on its website that its inpatient reviews and certifications are "based strictly on utilization management criteria and CMS rules and regulations." The EHR Physician Advisor Advantage, http://www.ehrdocs.com/ehradvantage.php (last viewed Mar. 24, 2014).

87. To make its inpatient review criteria appear superior and more accurate, EHR goes to great lengths to cause hospitals to believe that the UM Criteria are extremely inaccurate, and thereby cause a significant volume of inpatient cases to be inappropriately billed as outpatient. For example, EHR misrepresents to prospective clients that InterQual "rarely qualifies" cases for inpatient status and that therefore, a second level physician review by EHR is essential for "revenue integrity." This characterization of InterQual's screening criteria, which no doubt is intended to undermine the confidence hospitals and CMS place in InterQual, is false. Utilization of UM Criteria, like InterQual and Milliman, which have long been widely used and respected within the health care industry, routinely result in patients being admitted and billed as an inpatient.

88. In addition, the creators of InterQual train clients that InterQual's analysis of intensity of service and severity of disease is predictive of length of stay. It is also Dr. Polansky's understanding that Milliman explicitly forecasts lengths of stay. Medicare in or around 2008 elected to make these tools available to the Medicare medical review contractors, such as the RACs, MACs, and CERT, to assist with identifying and correcting improper payments.

89. EHR promotes and differentiates itself as a hospital compliance solution through its products and services that rely on its secret "EHR Logic." "EHR Logic" is marketed as a combination of four program components:

(1) 100+ "EHR Clinical Groups (ECGs)," – EHR's proprietary classification and case review criteria[3] sometimes known as "algorithms";

(2) "Our library of more than 7 million medical necessity reviews";

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[3] For purposes of this pleading, "case review criteria" means "EHR Clinical Group(s)."

(3) "Our training/testing/certification methodology"; and

(4) "Our QA [(Quality Assurance)] process."

90. In marketing its services, EHR also advises hospitals that, to properly perform a second review, it should be performed by a physician, and that EHR offers such expertise through its staff of physician advisors.

**2. EHR asserts that physicians are incapable of determining proper hospital status**

91. Under Medicare rules, only the treating physician can admit a patient to the hospital. (*See* paragraphs 51 to 54 above). However, many physicians have received inadequate training on Medicare's admission requirements. Thus, the attending physician's decision whether to admit can be incorrect or unsupported. And, since physicians are more focused on treating patients than billing decisions, EHR asserts that it is difficult to get physicians to correctly assign patient status determinations. EHR frequently exploits this issue in promotional materials and markets itself as the solution:

- "Physician response is 'variable' at best" (Investigate The World of Compliance – Strategies for Preventing & Appealing RAC Medical Necessity Denials at Slides 9-10);
- "Most treating physicians do NOT understand how to apply the regulatory and clinical definitions of Inpatient and Observation to correctly determine admission claim status" (*Id.*);
- In its promotional film, *Managing Observation Status – A Team Approach To Compliance and Revenue Integrity*, EHR included a dramatization of an attending physician simply deferring to the judgment of an EHR physician advisor who called the attending physician to point out that he incorrectly designated the patient for outpatient observation services rather than inpatient status;
- "It isn't that your physicians don't care – they just don't know the rules and have no idea what impact their uninformed decisions have on reimbursement." (Then EHR CEO Robert Corrato, *Managing Observation Status – A Team Approach To Compliance and Revenue Integrity*).

92. In discussing physicians' lack of engagement in determining proper hospital status, EHR's Chief Medical Officer, Ralph Wuebker, M.D., MBA advised that physicians "don't need to understand the nuances and the rules," rather "[t]hey need to understand how the grand picture works." Report on Medicare Compliance Vol. 21, No. 39 at 2 (Nov. 5, 2012).

93. In addition, EHR places heavy emphasis on the proficiency with which it interacts with attending physicians to ensure that they adopt (or rubberstamp) EHR's inpatient decision and order that the patient be admitted: "[EHR] reviews cases, speaks with admitting physician when needed, renders final decision based upon UR standards and documents decision in auditable format on chart or in UR documentation," and then "[t]reating physician changes order as appropriate." Investigate The World of Compliance – Strategies for Preventing & Appealing RAC Medical Necessity Denials at 12.

94. In the EHR promotional video, *Managing Observation Status – A Team Approach To Compliance and Revenue Integrity*, EHR provides two examples of how EHR interacts with physicians who assign patients to outpatient status. In both cases, EHR directed the attending physician that the patients were eligible for inpatient admission and instructed the physicians to write inpatient orders.

**3. EHR advises hospitals that by engaging EHR to perform second level reviews they are effectively shielding themselves from liability if the claims are later denied**

95. EHR has taken full advantage of the federal government's focus on reducing improper inpatient hospital admissions of patients who, under Medicare/Medicaid requirements, should have received care and been billed as outpatients. For years a cornerstone of EHR's promotional efforts to hospitals has been its detailed description of the arsenal of programs and procedures the federal government has been utilizing to target hospitals that improperly bill for

Medicare inpatient admissions and to recapture past overpayments. EHR dubs these programs and procedures collectively, "The Perfect Storm." "Surviving the Perfect Storm" is also the title of an educational program about RACs and medical necessity audits that EHR co-markets with the American Hospital Association ("AHA") – a nationwide hospital advocacy group consisting of thousands of hospitals and health care networks. According to EHR, in 2008 this program had 2,000 attendees from over 350 organizations, and generated over 180 educational CD requests. The Company has not been averse to playing on physicians' fears to generate clients either. For instance, in a related presentation to potential clients entitled, "Surviving the Perfect Storm: A Practical Approach to Patient Status, Medical Necessity and Revenue Integrity," EHR warned attendees that "[t]he RACs will investigate hospitals and they will eventually 'come after' physicians."

96. After instilling fear into hospitals, EHR then advises them that Section 1879 of the Social Security Act "provides for a waiver of liability of the provider if the provider could not have reasonably known that the services provided would not be covered by Medicare." It further advises that the hospital would qualify for the liability waiver – and thus should never have any inpatient claims denied – if the hospitals rely on EHR's inpatient certifications: "[a] consistent, comprehensive and compliant process of concurrent review must be present to ensure that the provider may benefit from the Limitation on Liability provided by the SSA." Investigate The World of Compliance – Strategies for Preventing & Appealing RAC Medical Necessity Denials at 20. Thus, EHR induces hospitals to utilize its services to transfer accountability and audit risk for inpatient hospital decisions to EHR. Indeed, in one commonly used EHR promotional slide, among the reasons hospitals use EHR is for "external validation & indemnification as well as for consistent return on investment."

97. In addition, as part of its concurrent medical necessity review, EHR provides hospitals a "Compliance Warranty":

98. The intensity of its marketing efforts is revealed in an internal EHR slide deck titled, [redacted] The slide deck outlines EHR's use of [redacted] which have provided EHR access to thousands of compliance professionals at thousands of health care providers.

99. EHR's marketing program has been incredibly successful, helping the company enjoy explosive growth over the past decade. According to the Philadelphia Business Journal, as of February 2004, the Company had recruited more than 60 hospitals in eight states as clients, employed 35 people, and generated revenue of about $5 million in 2003. *See* John George, *Docs prescribe Rx for ailing hospitals*, Philadelphia Bus. Journal, Feb. 20-26, 2004. By 2009, EHR provided services to more than 800 hospitals and health care providers around the country. In August 2010, when UnitedHealth Group's subsidiary Ingenix (subsequently renamed OptumInsight) acquired EHR for over $1.2 billion, the Philadelphia Inquirer described EHR as employing about 1,000, including 300 physicians, and generating revenue of over $100 million

per year. Presently, EHR states that its client base includes approximately 2,400 hospitals and health care systems nationwide (over half the hospitals billing Medicare in the country) and that it employs over 1,000 physician advisors.

100. According to EHR, it is the top physician advisor in the United States. To support this claim, EHR trumpets the following market share statistics:

- Over 50% of U.S. hospitals are clients;
- 71 of the top 100 integrated health networks use EHR; and
- 122 of the 289 academic teaching hospitals use EHR.

101. The following hospitals and health care systems located throughout the United States are believed to be EHR clients based upon the Company's own documents and information presented on its website:

- Bon Secours Health System

- Community Hospital of the Monterey Peninsula

- Indiana University Health

- Seton Healthcare Network

[redacted]

- Trinity Health

[redacted]

- The Valley Hospital

[redacted]

- Yale-New Haven Hospital

This is not an exhaustive list of EHR's clients, as the Company provides services to numerous other hospitals and hospital systems located throughout the country in addition to those listed above.

**B. EHR's Fraudulent Scheme To Generate Higher Medicare And Medicaid Reimbursements For Hospitals By Converting Large Volumes Of Cases That Fail The Utilization Management Criteria For Inpatient Status To Inpatient Claims**

102. Hospitals typically enter into a multi-year contract with EHR under which they agree to a [redacted] that incentivizes the hospital to refer more cases to EHR – [redacted] Some hospitals are currently paying EHR [redacted] per review.

103. While EHR's service is expensive, hospitals pay it because the increase in revenue attained from submitting cases as inpatient under Medicare Part A, rather than as outpatient under Medicare Part B, typically more than offsets the cost of the service.

104. To market to hospitals the substantial additional revenue they can receive by contracting with EHR to perform second level reviews [redacted]

[redacted]

105. Astonishingly, EHR estimated that, if the hospital were to engage EHR to perform a second level review [redacted] Significantly, in the simulation EHR assumed [redacted]

106. Most of EHR's hospital clients retain it to perform a second level review of all cases that fail the UM Criteria for inpatient status. And by doing so, they essentially delegate utilization review of cases that fail inpatient criteria to EHR rather than perform the reviews in-house. Additionally, receiving from a third party a basis to convert what are in fact outpatient cases to inpatient status is highly attractive to many hospitals.

107. EHR provides extensive instruction and oversight to the physician advisors it employs to review cases for hospital status "certification" in order to achieve consistently high rates of inpatient status decisions. As described on its website, EHR's determinations are delivered "through expert Physician Advisors who are specially-trained on Medicare/Medicaid

rules and regulations pertaining to observation and inpatient status." Corporate Overview, http://www.ehrdocs.com/aboutehr_corporateoverview.php (last viewed Mar. 24, 2014).

108. EHR instructs its physician advisors on CMS definitions of inpatient and outpatient services and what factors CMS requires be considered in determining how to designate a given case as inpatient vs. outpatient. These requirements, anchored in EHR's much touted case review criteria – the EHR ECGs – are the rigid criteria its physician advisors must apply to a particular illness, condition, or procedure in making the hospital status determination and lie at the heart of each compliance certification EHR prepares and hospitals follow.

109. EHR utilizes the same case review criteria regardless of whether the beneficiary is covered by Medicare, Medicaid or a commercial payer. When interacting with clients and prospective clients, EHR describes its determination of billing status for Medicaid cases as one of its "core" services, along with Medicare cases. Indeed, in bar charts EHR prepared for the [redacted] the disparity between payments for inpatient care versus outpatient observation care under Michigan's Medicaid program appears every bit as large, if not larger, than Medicare's. To the extent that any state Medicaid program defines inpatient status differently than Medicare, or follows guidelines for determining the appropriate hospital status that differ from Medicare's, Dr. Polansky never saw any evidence that EHR's physician advisors took such differences into account when applying its case review criteria. EHR, however, told hospital customers that any such individual differences within the state Medicaid programs were taken into consideration when it reviewed cases for inpatient or outpatient observation certification.

110. The case review criteria are applied strictly by EHR physician advisors and compliance with them is vigorously monitored. EHR's physician advisors do not have discretion

to deviate from the EHR criteria. EHR provides three to four weeks of extensive onsite training and testing to ensure physician advisors comply with the EHR case review criteria.[4]

111. This training and testing program also includes Computer Based Training (CBT) for each case review criteria set. Physician advisor's must pass tests for each criteria set including new ones as they are developed. Achieving passing scores is a condition of employment. These tests typically include [redacted] EHR trains physician advisors to improperly rely on identifying patients as [redacted] rather than following CMS's time based requirement.

112. As part of ensuring strict application of EHR's criteria, [redacted] EHR also monitors the physician advisors to ensure that they rigidly apply the EHR criteria. This is in part how EHR has been able to standardize and generate extraordinarily high rates of inpatient certifications. Hence, the inpatient certifications EHR provides to hospitals are not the product of nuanced and individualized physician judgment. To the contrary, EHR's physician advisor certifications are done rapidly and are guided by a formulaic and mechanical process – strict application of the EHR case review criteria.

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[4] Dr. Polansky was only allowed to attend the first two weeks of the intensive onsite training program.

[5] In addition, physician advisor bonus compensation is determined, in part, by the volume of reviews completed. [redacted] slows the team down and thus results in a reduction of the physician advisor's compensation, discouraging deviation from the EHR case review criteria.

113. Thereafter EHR transmits to the hospital a real-time summary of the case, including what it refers to as a "certification" of medical necessity for a specific billing status. In the early part of the relevant period, that document was titled, "Compliance Determination," and during 2011 it was referred to as an "EHR Recommended Medical Necessity Determination." A typical EHR medical necessity certification provides that it is for use by the hospital business office in connection with "ensur[ing] compliance with CMS policy regarding Inpatient Admissions and Observation Services." Further, it provides that the certification is not to be used to limit clinical services provided to the patient.

114. Upon receipt of EHR's inpatient certification, the hospital integrates it into the patient's medical record to support the inpatient claim submitted for payment. The hospital does not, however, provide the inpatient certification with the claim for payment that it submits to the Medicare Administrative Contractor or the appropriate state Medicaid program.

115. In almost every instance, when the hospital client submits for payment the Medicare and Medicaid claims that EHR has reviewed and certified for inpatient status, it adopts that inpatient billing status determination notwithstanding the fact that the hospital's first level review has typically determined that outpatient status with observation services was appropriate and sometimes, the attending physician did as well. Indeed, as EHR explains to clients and prospective clients, when EHR reaches an inpatient decision that differs from the decision of the attending physician, EHR and the hospital case managers are generally successful in obtaining a new order from the physician that is consistent with EHR's decision. Thus, for virtually all cases it reviews, EHR's inpatient certification is **determinative** of the billing status that the hospital submits to the Government Payers. EHR provides tracking reports to hospitals to ensure that hospital status orders match the certifications.

116. The ECGs/case review criteria were initially developed by Tom McCarter, M.D. ("McCarter"), EHR's Chief Clinical Officer (CCO), with assistance from a graduate student and an administrative assistant. McCarter and other leaders at EHR recognize how critical these case review criteria are in making EHR a viable enterprise, and they are widely referred to at EHR as the "secret sauce."

117. Although proprietary, UM Criteria for inpatient status, such as InterQual and Milliman, are shared with users and are available for public scrutiny. Unlike InterQual or Milliman, which hospitals apply themselves to a given case, EHR does not share with its clients the case review criteria upon which it relies in determining billing status for the hospital. And physician advisors are trained to never share the "secret sauce" with clients. For instance, in an internal PowerPoint from April 2008 titled, [redacted] which discussed the case review criteria for certain [redacted]

118. What EHR does tell hospitals, however, is that its medical necessity/compliance review is a "complex physician medical judgment" taking into consideration these factors:

- CMS requirements regarding medical necessity for hospital admission
- Applicable Medicare regulations and guidance
- Applicable evidence based data and expert guidance
- Published medical literature
- [EHR's] national experience with the appeals process

119. In truth, however, and as EHR and the UHG Defendants know or recklessly disregard, EHR does not follow CMS requirements when reviewing cases to determine inpatient or outpatient hospital status. Some CMS guidance it simply ignores. Other guidance it places

myopic emphasis upon. And it affirmatively mischaracterizes the nature and quality of outpatient observation services. EHR's blatantly incorrect interpretation and application of CMS requirements is motivated by a desire for profits. By improperly applying CMS payment requirements in a manner which leads to the certification of thousands upon thousands of cases for inpatient status that otherwise would not have qualified for such status, EHR has fraudulently been able to boost the revenues of its client hospitals (via increased Medicare/Medicaid payments), generate increased demand for its services and thereby its and the UHG Defendants' own profits.

120. That the payment process is by and large an honor system is an underlying factor contributing to the success of EHR's fraudulent scheme to convert outpatient observation cases to inpatient cases. Claims for payment are typically accepted at face value by the Medicare contractor or state Medicaid agency. And underlying medical records, such as the EHR certification, are not submitted with the claim. The likelihood that any given claim is going to be audited is very remote.

121. Inasmuch as such a huge percentage of U.S. hospitals utilize EHR to determine whether Medicare and Medicaid beneficiaries will be admitted as inpatients – EHR, by its own calculation, has performed over 10 million reviews – the standards EHR applies in making such decisions, which are flawed for the reasons stated herein, have nevertheless acquired the patina of legitimacy and become the de facto standards in this niche industry. EHR leverages its database of inpatient versus outpatient determinations in order to accelerate the adoption of its services and the EHR Logic. Specifically, EHR tells hospitals that by relying upon its enormous historical database of hospital status determinations as the standard, EHR can provide "OBS Benchmarking" so that for each type of medical case, hospitals will know the ratio of inpatient

versus outpatient observation determinations it can anticipate. EHR's certifications thereby have tainted and corrupted the ability of the Government Payers and the hospitals to establish and use legitimate benchmarks to calibrate the rates of inpatient versus outpatient payment, and have the potential of tainting hospital inpatient admission determinations even beyond those for which EHR has issued certifications.

**1. EHR's case review criteria violate CMS's requirements**

**a. *EHR's case review criteria fail to address CMS's 24-hour benchmark***

122. The Medicare Benefit Policy Manual states that the benchmark for determining whether a patient should be admitted as an inpatient is whether or not he or she is expected to need hospital care for 24 hours or more, in which case admission as an inpatient should generally be ordered.[6] Other patients should be treated in outpatient status. (*See* paragraph 48 above). EHR's case review criteria do not integrate this conceptual framework and provide no instruction or guidance as to how the CMS 24-hour benchmark should be applied to a given set of symptoms or diagnosis. In contrast, EHR exclusively focuses its review on patient risk at the time of presentation to the hospital for services.

**b. *EHR's case review criteria disregard the fact that observation services are intended for patients whose clinical trajectory is uncertain***

123. The EHR case review criteria employed categorically disregard the payment rules which direct that observation care is appropriate when treating patients whose short term clinical

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[6] The 24-hour benchmark begins once the physician has adequate information to accurately predict length of stay – *i.e.*, information generated from observation services that are provided while the patient is in outpatient status. This is why Medicare and its contractors typically describe the benchmark as 24-48 hours in educational pieces discussing the differences between inpatient and outpatient status. In 2013, through 42 C.F.R. § 412.3(e)(1), CMS clarified that the 24-hour benchmark equals two midnights and that, in general, when a hospital stay is less than two midnights inpatient status is inappropriate.

trajectory is uncertain. Emergency room visits for patients with conditions such as congestive heart failure, asthma, and chronic obstructive pulmonary disease are examples of types of cases where aggressive short term outpatient therapy can prevent the need for inpatient admission. For this subset of patients, observation services spanning a period of 24 to as many as 48 hours is required – not inpatient admission. EHR and its case review criteria fail to address this requirement and the underlying fact that patients can expect to have the same therapeutic interventions performed to address his/her condition in the hospital regardless of whether they are outpatient or inpatient status. EHR's reliance on [redacted] and payment certification for inpatient claims directly violates and is contrary to the design and implementation of the CMS hospital payment system. *See* MBPM, ch. 6 § 20.

c. ***EHR's case review criteria fail to await the results of pivotal diagnostic studies before determining inpatient status***

124. CMS's Medicare Benefit Policy Manual lists four factors "to be considered" in making a determination whether to admit a patient as an inpatient. Two of these four expressly pertain to diagnostic studies: **first**, the need for diagnostic studies that are outpatient services (*i.e.*, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and **second**, the availability of diagnostic procedures at the time when, and at the location where, the patient presents. The critical nature of these factors is clear. The purpose of observation is to determine the need for further treatment or for inpatient admission. *See* MBPM, ch. 6 § 20.6(B) (Rev. 107, 05-22-09). An informed determination can be reached if, and only if, the results of appropriate diagnostic studies can be factored into the attending physician's analysis. Thus, observation care is required in those cases in which key diagnostic test results are expected within 24 hours.

Frequently emergency room visits for patients with conditions such as chest pain or syncope are examples of the types of cases where awaiting the results of short term diagnostic studies is essential to calibrate actual patient clinical severity and the necessity of inpatient admission. However, EHR's case review criteria, in general, violate the requirement that a provider must await the results of key diagnostic outpatient tests prior to making an informed decision about the need for inpatient admission. EHR instead relies on [redacted] and certifying inpatient status. This directly violates, and is contrary to, the design and implementation of the CMS hospital payment system.

125. EHR misinforms and misleads its physician advisors about the pertinent CMS statutory and interpretive guidance. The Company instructs physicians that Chapter 1 § 10 of the Medicare Benefit Policy Manual emphasizes "several key points." Of these "key points," EHR characterizes only one as critical, namely, [redacted] In contrast, EHR makes not a single reference to the critical role of awaiting pivotal diagnostic test results in properly assessing the medical necessity for inpatient admission and the required assignment to the most economical and medically necessary hospital status. More generally, EHR and its case review criteria fail to recognize the material fact that if a patient is receiving outpatient observation services within a hospital, the patient can expect to have the same tests performed to help assess and reassess his/her condition that would be performed if he/she were admitted as an inpatient. Likewise, EHR never discloses the material fact that "[i]n most circumstances, observation services are supportive and ancillary to the other separately payable services

provided to a patient" on an outpatient basis. MBPM, ch. 6 § 20.6(B) (Rev. 107, 05-22-09); *accord* MCPM, ch. 4, § 290.5.1 (Rev. 1760, 06-23-09).

126. EHR's promotional PowerPoints indicate that when communicating with hospitals, EHR deliberately disregards the requirements that hospitals await the results of diagnostic testing in arriving at an informed medical judgment as to whether inpatient or outpatient observation services is appropriate. The evolution of a particular PowerPoint slide is telling. In Summer 2008, Wayne Grodsky, V.P. of Sales, gave to hospitals a PowerPoint presentation titled "[redacted]" The slide, which quotes Chapter 1, § 10 of the Medicare Benefit Policy Manual, lists the same factors for consideration as does § 10: (1) severity of symptoms, (2) risk of adverse event, (3) need for diagnostic studies, and (4) availability of such studies. [redacted]

**d. *EHR misleadingly instructs its physician advisors that observation services constitutes a lesser intensity or scope of care***

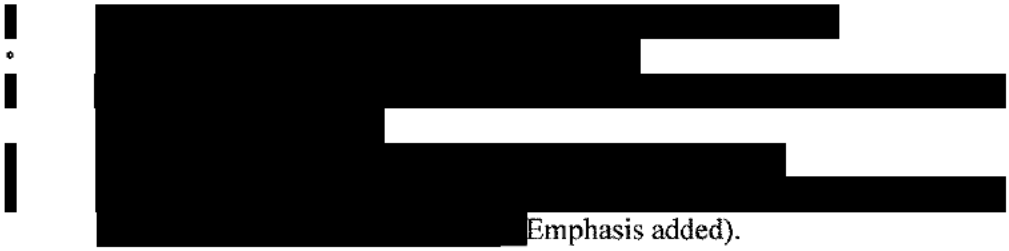
127. Whether a hospital classifies a Medicare or Medicaid patient as an outpatient receiving observation services or as an inpatient is a choice that pertains solely to billing, not to the scope or intensity of care which the patient receives. EHR knows this. Nevertheless, to generate more inpatient "certifications" EHR seeks to misinform its advisory physicians, instructing them that patients who are certified for outpatient observation services are at risk of receiving services of less intensity and scope from the hospital than would be the case if they

were admitted as an inpatient. An example of such misinformation is the following instruction taken from a 2010 EHR training memorandum:

The above statement is materially false and misleading. Whether a patient is an outpatient receiving observation services or admitted as an inpatient, the hospital will act in that particular patient's best interest. *See* 42 U.S.C. § 1320c-5 (Hospitals receiving Medicare or Medicaid payments must assure that services provided to covered patients "will be of a quality which meets professionally recognized standards of health care"); *see also* 65 Fed. Reg. 18,434, 18,452 (Apr. 7, 2000) (no matter how a procedure or service is classified for billing purposes, CMS expects that the hospital will "act in that patient's best interests").

128. The scope and intensity of care patients receive from hospital observation services will generally be indistinguishable from the care he or she would receive if classified as a hospital inpatient. For each patient, the same tests and treatments are administered, the same nursing care is given, and the same bed and board are provided in the outpatient setting as would be administered in the inpatient setting. The difference lies in how the Government Payer is billed, and the hospital is paid. Consistent with this statutory and regulatory framework, Medicare guidelines contemplate that outpatient observation patients will be receiving multiple services, and that the observation services will generally be ancillary to *other services* they receive (such as diagnostic studies, lab results, and treatment). In fact, Medicare provides that outpatient observation services can be administered in the context of high-level, Type-B emergency department visits, and even critical care, both of which typically entail extensive testing and or treatment. MCPM, ch. 6 § 290.5.1 (Rev. 1760, 06-23-09).

129. Publicly, EHR has expressly acknowledged the lack of any disparity between inpatient and outpatient observation services. For instance, EHR made the following points in a slide from a recent hospital marketing presentation:


Emphasis added).

130. EHR's knowledge of the fact that inpatient care generally mirrors outpatient observation care is further supported by its involvement in the *Bagnall v. Sebelius* class action. In November 2011, seven Medicare patients (or the executors of their estates), filed a putative class action against the Secretary of Health and Human Services, Kathleen Sebelius, alleging on multiple statutory and Constitutional grounds that they were wrongfully deprived of Medicare Part A inpatient coverage when assigned to outpatient status. *See Bagnall v. Sebelius*, No. 3:11-cv-1703-AWT (D. Conn.). Significantly, the plaintiffs did not allege that observation services provided in outpatient status are in any way different in intensity and scope of care than the services that would have been provided had the patients been assigned inpatient status. To the contrary, they asserted that, "[b]eneficiaries on observation status generally receive the same treatment as beneficiaries who have been formally admitted, but they are considered outpatients by the Secretary [of DHHS]." What underlies plaintiffs' lawsuit is instead the potential for outpatient observation patients to be held personally responsible for more medical costs under Medicare Part B than inpatients undergoing identical treatment under Medicare Part A. The Center for Medicare Advocacy, Inc. represents the plaintiffs in *Bagnall*. The government's motion to dismiss the case was granted in September 2013. *See* 2013 WL 5346659 (D. Conn.

Sep. 23, 2013). The plaintiffs have appealed that ruling. Dr. Polansky has learned that EHR was well aware of, and had endorsed and/or promoted, this lawsuit before it was filed. In fact, in January 2012, when Dr. Polansky learned of the lawsuit and forwarded the information onto CCO Tom McCarter. McCarter replied to Dr. Polansky via email: [redacted]

**2. EHR's case review criteria lack scientific integrity**

**a. *Flawed integration of patient risk assessment tools into the EHR Logic***

131. The ECG case review criteria falsely [redacted] as a basis to certify cases as inpatient. These tools in general are not designed or validated to predict length of stay, the primary driver of a hospital status determination.

132. As an example, EHR's case review criteria for kyphoplasty [redacted] and thus eligible for inpatient status. Kyphoplasty is not on the Medicare Inpatient Only List, which CMS developed to identify the majority of cases requiring an inpatient stay. [redacted]

133. Dr. Polansky is not aware of any research that has identified the [redacted] as being useful in discriminating between short stays and extended stays in the hospital. Nonetheless, EHR physician advisors are required to rely upon this tool to certify inpatient

status. The inventory of risk assessment tools integrated into the EHR ECGs, including the [redacted] is discussed in an EHR document titled, [redacted]

134. Furthermore, it is likely that EHR's inpatient kyphoplasty certifications, and the dramatic increase in revenue hospitals derived from them, is stimulating unnecessary surgeries, and thus putting patients in harm's way. The medical literature, including the preeminent New England Journal of Medicine, have identified kyphoplasty in particular as a potentially over-utilized procedure creating unnecessary clinical and financial risk for many elderly patients.

**b.** ***EHR's case review criteria are over-inclusive checklists of risk factors***

135. EHR's case review criteria often consist of a checklist of risk factors that focus on [redacted] These checklists have been engineered to allow thousands of cases to be certified as inpatient when evaluation and treatment could have been effectively provided, billed, and paid more economically on an outpatient basis. For instance, for some conditions, [redacted] and thus require inpatient treatment. These factors can be so over-inclusive that inpatient treatment will be deemed reasonable and necessary for the vast majority of Medicare or Medicaid beneficiaries who present with any of these conditions. Yet EHR applies these factors as though they accurately predict extended lengths of stay.

136. CMS recently reiterated that it is incorrect to make inpatient determinations based upon risk assessments that are predicated on the beneficiaries' "benign or latent past medical history." 78 Fed. Reg. 50,947 (CMS Aug. 19, 2013) (comments to final rules). To the contrary, for purposes of admissions decisions, "risk must relate to current disease processes or presenting symptoms." *Id.* CMS further commented:

> It is up to the physician to make the complex medical decision of whether the beneficiary's risk of morbidity or mortality dictates the need to remain at the hospital, because the risk of an adverse event would otherwise be unacceptable under reasonable standards of care, or when the beneficiary may be discharged home. If the resultant length of stay for medically necessary hospitalization is expected to surpass 2 midnights, the physician should admit the patient as an inpatient.

*Id.* In contrast, EHR's clinical review criteria frequently rely on benign and latent past medical history as opposed to factors directly and significantly related to the determination of anticipated length of stay.

**c. *EHR has not validated the utility of its ECG criteria in predicting length of stay***

137. Based on discussions he had with McCarter, Dr. Polansky is not aware that EHR has commissioned or undertaken any systematic analysis to assess the utility of any of the ECG criteria in accurately forecasting the expected length of stay. Dr. Polansky is also not aware of any independent scientific advisory board convened by EHR to assess the integrity of the EHR ECGs and hospital status certification decision making.

138. By design, EHR has not shared the criteria with clients or subjected the criteria to any meaningful internal or external validation. Dr. Polansky in fact suggested to EHR's leadership that they should validate the ability of the ECG criteria to satisfy the Medicare 24-48 hour benchmark. He received no response. Given the enormous and detailed database of cases that EHR has stockpiled, including which ECG criteria were met for individual cases, case length

of stay, coupled with the analytic capabilities of EHR, this was a necessary and achievable task. EHR wilfully disregards that its case review criteria generate huge numbers of short stay inpatient cases.

**d. *EHR's fraudulent case review criteria for chest pain***

139. An illustration of EHR's fraudulent case review criteria to determine Medicare/Medicaid hospital status is found with cases of chest pain. Chest pain is a frequent reason for presentation to an emergency room. The attending physician in such a case will undertake to answer the question of whether the underlying cause is serious, such as a heart attack, or more benign. In general, within 24-48 hours diagnostic information becomes available that provides the answer and determines the need for inpatient admission. And, as previously alleged, under the applicable Medicare requirements, adequate diagnostic information is central to the inpatient determination. In addition, although over 5 million patients present with chest pain in emergency rooms each year, ultimately a large majority are quickly diagnosed as not having a cardiac event requiring hospitalization and therefore can be safely evaluated and managed with observation services and then sent quickly home.

140. In contrast, EHR applies its chest pain case review criteria to such a case. But this case review criteria entirely ignores the critical role that diagnostic testing plays in determining the appropriate payment status for a chest pain patient. EHR's case review criteria includes a checklist of [redacted] and certifies billing as an inpatient.

141. Indeed, Dr. Polansky was told by Dr. McCarter that at an earlier point in time, before EHR concluded it created too much business risk, the presence of just [redacted]

[redacted] to conclude that inpatient treatment was reasonable and necessary. But for many of these patients, if diagnostic information were taken into account, the information would ultimately "rule out" a serious acute clinical condition. Medicare requires that hospitals manage and bill these patients as outpatients. Furthermore, for many patients for whom EHR produces an inpatient Medical Necessity Determination, not a single enumerated factor that EHR relies on to reach that determination pertains to the actual severity of the patient's acute condition or the intensity of services provided.

142. [redacted]

143. [redacted] The certification EHR provided the hospital for incorporation into the patient's medical record does not comply with the Medicare Manual instruction. It falsely states:

[redacted]

144. [redacted]

Indeed, because EHR rigidly applies its case review criteria, physician advisors are required to certify inpatient status for any patient experiencing chest pain who satisfies these three factors. In contrast, the Milliman/InterQual screening criteria appropriately failed this case for inpatient status. Most importantly, under Medicare payment policy, this is a patient who required hospital outpatient observation services but for whom inpatient admission was not reasonable and necessary nor the most economical setting for care.

145. This case was part of a group of short inpatient stay cases reviewed by NGS – a MAC responsible for identifying and correcting improper payments – during an onsite review guided by analysis of claims data. Following its onsite audit of medical records, NGS sent a letter dated November 23, 2011 to the Senior Vice President of Operations-Administration for the [redacted] informing the hospital that it had concluded that inpatient level of care was not supported for the case described above as well as others. The contractor's case summary stated:

[redacted]

146. The conclusion that the patient described in the preceding paragraph is not eligible for inpatient payment is underscored by the findings Highmark Medicare Services (a MAC) reported in comparable circumstances. In late 2010, Highmark published a policy article that discussed improper payment results from the authoritative Medicare Comprehensive Error Rate Testing (CERT) Contractor. In particular, Highmark highlighted a series of one day admissions that were incorrectly billed as inpatient. Highmark included examples of two patients complaining of chest pain, who were admitted inpatient **prior to diagnostic testing results being available to determine if an acute cardiac condition was present**. These results quickly established no acute cardiac condition was present and the patients were discharged. Outpatient observation care, not inpatient care, was the correct billing methodology.

147. Likewise, the Medicare Quality Improvement Organizations (QIOs), the Medicare contractors previously responsible for ensuring that payment is made only for inpatient hospital care that is medically necessary and provided in the most economical manner, provided similar guidance on payment status for hospital services provided to chest pain patients. Qualidigm, the QIO for Connecticut, directed hospitals to assign emergency department patients presenting with chest pain to inpatient billing status only after pivotal diagnostic studies reveal acute cardiac disease. In fact, Qualidigm noted that five out of six chest pain patients who present to the emergency room do not have an acute cardiac condition requiring inpatient admission. *See*

Qualidigm presentation entitled, "Reducing Admission Denials Through the Promotion of Hosp. Observation Status" (Dec. 6, 2009).

148. Furthermore, a compliant approach to chest pain status decisions is described in a November 2009 article entitled "Using Observation Services" published in the American College of Physicians' *ACP Hospitalist*:

> Take the example of a 67-year-old patient seen in the emergency department with gradual onset of chest pain over the last two hours, a normal EKG and an elevated troponin level. Because the cardiac enzymes are elevated, inpatient is appropriate. However, in the case of a 64-year old patient seen in the emergency department with chest pain, slight ST-segment elevation on EKG, and negative cardiac enzymes, classification as an outpatient with observation services is appropriate. The physician could observe serial enzymes and EKG in outpatient observation. If the physician later determined that acute inpatient care was necessary, he or she could always admit the patient, documenting the change clearly in the physician orders.
>
> A physician should not automatically admit a patient because 24 hours have elapsed. There must be a medical need for an inpatient admission.

D. Hale, *Using Observation Services*, ACP Hospitalist (Nov. 2009).

149. Similar EHR case review criteria are used to certify inpatient care in place of the required use of observation services for a range of frequent emergency room presentations (and direct admissions) where the patient's underlying diagnosis is indeterminate or there is an opportunity for short term therapy to address the patient's condition. EHR has case review criteria for a range of these frequent types of emergency room presentations beyond chest pain, including for syncope, gastrointestinal bleeding, [redacted] and congestive heart failure. EHR routinely describes these types of cases as the "gray zone" and broadcasts to hospital clients that these types of cases account for billions of dollars of Medicare payments that are ripe for conversion to inpatient status. It also includes chest pain, anemia, [redacted] back pain, mastectomy, prostatectomy, and laparoscopic appendectomy.

150. It should be noted that, with regard to some of the emergency room cases that EHR certifies for inpatient or outpatient observation services, the patient does not even meet the Medicare or Medicaid payment requirements for outpatient observation services.

### 3. EHR provides false inpatient certifications for numerous types of outpatient surgical procedures

151. Beginning in 2008, EHR added review products for outpatient surgical procedures. EHR created and applies its case review criteria to certify a range of frequent outpatient surgical procedure cases as inpatient status. In addition, EHR's case review criteria result in many surgical procedure cases being certified as inpatient status when the case does not even satisfy the Medicare or Medicaid payment requirements for outpatient observation services.

152. The outpatient surgical procedures for which EHR certifies hospital status range from interventional cardiology (*e.g.*, pacemakers, defibrillators, and percutaneous cardiac interventions) to orthopedics/neurosurgery (*e.g.*, kyphoplasty).

153. As part of the inpatient admission requirements, Medicare has longstanding requirements for outpatient surgery, as the term is described below:

> When patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered outpatients for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.

MBPM, ch. 1 § 10 (Rev. 1, 10-01-03).

154. Furthermore, Medicare has established an inpatient only list for a range of surgical procedures that it has analyzed and concluded that inpatient admission is likely and necessary. Although Medicare does not preclude rare and exceptional patients undergoing procedures not on the inpatient only list from being admitted to the hospital, the Medicare regulations do not contemplate assigning significant numbers of these patients to inpatient status

based on an inventory of historical information including comorbidities. In addition, for rare patients who undergo complications during surgery or during recovery and require extended stays, Medicare rules enable observation services to be provided and billed, or, as necessary, inpatient admission to be provided and billed.

155. As part of outpatient surgery case reviews, EHR collects clinical data prior to the procedure to assess risk and assign inpatient status to cases that are identified as [redacted] As discussed, EHR's approach is inherently flawed because the review criteria to assess risk (1) frequently fail to accurately predict length of stay, and (2) typically fail to integrate critical information about patients' stability during the operative and perioperative period.

156. In estimating risk for outpatient surgical cases, the EHR case review criteria like other criteria previously discussed, also frequently rely upon information related to [redacted] that do not significantly impact the patient's current clinical status and length of stay. EHR emphasized the significant role [redacted] play in its inpatient certifications in a 2011 implementation presentation to clients as follows:

[redacted]

157. In client presentations EHR also emphasizes incorrectly that InterQual rarely qualifies surgical procedure cases as inpatient.

158. EHR and its case review criteria's disregard of the regulatory structure governing hospital status for outpatient surgery is illustrated in an inpatient certification that it provided to [redacted]. This was an inpatient certification for a [redacted]

[redacted]

159. [redacted]

160. This [redacted] case, which is not on the Medicare inpatient only list, does not meet Medicare's inpatient status requirements, which are set forth in Part IV-C-1 above, including meeting the required benchmark of 24 to 48 hours. [redacted] Yet, the EHR physician advisor mechanically applied EHR's risk assessment criteria, concluded that the patient was [redacted] and certified the patient as an inpatient. [redacted] which leads to certification of the vast majority of these patients as inpatients. These certifications cause hospitals to submit false claims for inpatient services.

161. As the National Institute of Health's, National Heart, Lung, and Blood Institute has observed, cardiac ablation is generally a routine outpatient procedure that carries a low risk of complication:

> What To Expect After Catheter Ablation
>
> After catheter ablation, you'll be moved to a special care unit where you'll lie still for 4–6 hours of recovery. Lying still prevents bleeding from the catheter insertion site.
>
> You'll be connected to devices that measure your heart's electrical activity and blood pressure. Nurses will regularly check these monitors. Nurses also will check to make sure that you're not bleeding from the catheter insertion site.
>
> Going Home
>
> Your doctor will decide whether you need to stay overnight in the hospital. Some people go home the same day as the procedure. Others need to stay in the hospital longer.

National Heart, Lung, & Blood Institute, http://www.nhlbi.nih.gov/health/health-topics/topics/ablation/after.html (last viewed Mar. 19, 2014).

162. EHR Senior Medical Director, Evan Pollack, M.D., has acknowledged that cardiovascular procedures are "high-dollar, short-stay events," and that "most patients [who undergo these procedures] are discharged the next day." Report On Medicare Compliance, Vol. 21 No. 3 at 1 (June 18, 2012).

163. EHR's review criteria for the outpatient surgical procedure cardiac stenting, which EHR has titled, [redacted] are similarly designed to certify the vast majority of patients as "[redacted]" and therefore as inpatient status. For example, as part of this criteria set there are instructions to the physician advisor [redacted]

164. EHR conducted an internal analysis of its early experience in reviewing interventional cardiac procedures. [redacted] The results are remarkable because they demonstrate the [redacted]

[redacted] The 25% of cases lacking adequate documentation are false claims by EHR's own admission.

165. [redacted] The remaining claims are false claims. Medicare as a condition of payment requires that all services be documented adequately in the medical records. *See, e.g.*, 42 U.S.C. § 1395l(e) and the regulations CMS promulgated thereunder.

**4. EHR told a family of hospitals that it would focus on assigning surgical "procedures that tend to have shorter stays" to inpatient status**

166. In 2008, EHR conducted a retrospective [redacted]

167. EHR's reliance on these three criteria demonstrates that EHR was focused not on increasing [redacted] compliance rate but rather solely and illegally on revenue enhancement. That EHR was proposing to focus its medical necessity/compliance review process on those

procedures in which short stays were common, as opposed to longer stays, is particularly troubling because those are the very procedures for which, under CMS guidelines, inpatient admission is likely not justified. In fact, that the length of stay at [redacted] for these procedures in the prior year had been short illustrates that these procedures required classification as outpatient and that any increase in the percentage of outpatient observation cases for these procedures was actually in compliance with Medicare requirements. For EHR, however, all that mattered was that, under Medicare's DRG system of reimbursement, it is far more lucrative for the hospital to convert outpatient surgical procedures from outpatient or outpatient observation to inpatient.

**5. EHR's lucrative appeals business**

168. Throughout the relevant time period a significant portion of EHR's business has included appealing denied inpatient claims on behalf of hospitals. EHR is formally delegated the authority to submit these claims for payment as part of a Business Associate contract. This includes appealing denied inpatient claims that EHR did not previously review as a physician advisor. As to this additional subset of claims, EHR applies the same flawed case review criteria that it applies when reviewing claims in its capacity as a physician advisor.

169. For all denied claims for which EHR represents the hospital in connection with the appeals process, EHR directly submits the claim for payment to Medicare or the appropriate state Medicaid program.

170. The Medicare administrative appeals process consists of four levels:

LEVEL 1 – administered by MACs;
LEVEL 2 – administered by CMS Qualified Independent Contractors (QICs);
LEVEL 3 – administered by Medicare Administrative Law Judges (ALJs);
LEVEL 4 – administered by the Medicare Appeals Council.

171. During the pilot years of the Medicare RAC program from March 2005 to March 2008, hospital appellants perceived that there was a high success rate for cases reviewed by an

ALJ.[8] However, these were cherry picked cases, only a small percentage of cases denied by the RACs ultimately were seen by the ALJs. In a November 2012 report entitled "Improvements are Needed at the Administrative Law Judge Level of Medicare Appeals," the HHS OIG identified systemic failures in the ability of the government to organize efforts to defend payment denials:

(a) A lack of specialization among ALJs who instead decide appeals involving all Medicare program areas;

(b) A tendency by ALJs to interpret Medicare policies less strictly than QICs;

(c) Rare participation by CMS in ALJ appeals (9% in Medicare Part A appeals), which provided hospitals free rein to make arguments to which there was no opposition and precluded CMS from submitting evidence, examining witnesses, or appealing to the next level; and

(d) A high volume of appeals by certain parties.

172. The systemic weaknesses highlighted in the November 2012 OIG report emboldened EHR to disregard the outcome in the first levels of appeal and misrepresent the basis for success at the ALJ level. The EHR marketing machine advised hospitals to be aggressive in allowing it to appeal denied inpatient claims up through the ALJ level. An additional self-serving byproduct of appealing vast numbers of inpatient claim denials has been to clog up the ALJ hearing system. The current delay is upwards of four years for a case to reach an ALJ. Some EHR clients for multiple years have never obtained a decision on a denial at the ALJ level but have nevertheless continued their relationship with EHR in reliance upon its false promise that the hospital will ultimately prevail on millions of dollars of claims awaiting ALJ review.

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[8] CMS challenges this purported "success" in a December 2012 report entitled, "Medicare Fee-For-Service Recovery Audit Program Myths" in which the agency reported that: "To date, only 2.4 percent of all 2010 claims collected have been both challenged and overturned on appeal. Health care providers have appealed 8,449 claims to date, which constitutes 5 percent of all claims collected in FY 2010." CMS, *Medicare-Fee-For-Service Recovery Audit Program Myths* at 2 (Dec. 17, 2012).

However, the vast majority of hospital status denials have been upheld at the first and second levels of appeal.

173. Recent initiatives aimed at developing and providing training to ALJs and QICs, reducing meritless appeals, and boosting CMS's participation in ALJ appeals have caused the success rate of appellant hospitals, many of which are represented by EHR, to drop significantly. EHR aggressively markets having a high ALJ success rate of 80% to 90% to generate new clients and induce hospitals to utilize EHR's appeal management service. However, since the system has undergone reforms, EHR, through its sophisticated tracking systems, is undoubtedly aware that these levels of success have not been sustained and no longer apply.

174. With regard to hospitals/EHR's appeals of RAC-initiated denials, now that CMS is more engaged in defending payment denials, it is Dr. Polansky's understanding that hospital success rates in overturning the RACs' denials at the ALJ level have plummeted. Dr. Polansky is unaware of a single instance where EHR provided hospitals the denial appeal success rates since 2010 when the RAC program was implemented nationwide.

175. However, Relator's January 2013 review of more recent Medicare Appeals Council decisions available on Westlaw paints a very different profile of hospitals' success at the ALJ level. Approximately 67 of the decisions involved determinations as to whether hospital services billed to Medicare were properly billed as inpatient or outpatient claims. Significantly, inpatient status was upheld in only 6 of the 67 cases. And, in contrast, in more than half the cases (38) the Council determined that the services should have been provided on an outpatient observation basis rather than as an inpatient admission. The rest of the cases were remanded to the ALJ for further proceedings, with instructions for the ALJ to follow the correct rules, statutes and guidelines. Notably, EHR was the physician advisor to the billing hospital in at least 6 of the

67 decisions. Among these six, none were ruled inpatient, one was ruled outpatient, three were remanded with instructions to use the proper legal framework and two were dismissed because the hospital's appeal was untimely.

***EHR's fraudulent Medicaid appeals***

176. The fraudulent EHR appeals business is illustrated in three short stay appeals submitted to the State of South Carolina. South Carolina relies on InterQual as its first level review criteria. Unlike Medicare, South Carolina also requires a physician peer review prior to any payment denial. The review of claims is contracted out to a Medicaid Recovery Audit Contractor.

177. [redacted]

178. [redacted]

179. [redacted]

[redacted]

[redacted]

[redacted]

**6. EHR's internal documents reveal intense discussions about the integrity of EHR's hospital certification program**

180. The extent to which EHR had failed to comply with CMS guidance in making its inpatient versus outpatient observation determinations – and EHR's knowledge of its failure – was colorfully captured by EHR's Associate Vice President of Strategic Accounts, Ann Kessinger, in an email she sent to CCO McCarter in January 2012. Kessinger had received a copy of a flow chart prepared by a government-approved MAC, WPS, that explained how the inpatient vs. outpatient observation determination should be made in accordance with CMS requirements. The flow diagram highlighted the 24 to 48 hour outpatient window to assess response to therapy and complete essential diagnostic testing. Kessinger wrote to McCarter,

[redacted]

181. Likewise, on February 1, 2012, in anticipation of responding to a Medicare audit of a client hospital, McCarter asked Dr. Polansky to provide him [redacted] He continued, [redacted] It is rather astonishing that in the course of making his request, McCarter has effectively admitted that EHR's so-called expertise in making appropriate concurrent medical necessity determinations is a sham and that its case review criteria, which EHR has utilized for

years to make its medical necessity billing determinations – and which constitute the core of its business model – lack a rational basis and are not in compliance with Medicare and Medicaid law, regulation, and guidance.

182. In response to McCarter's February 1, 2012 request for [redacted] Dr. Polansky provided McCarter a memo on February 9, 2012 in which he informed McCarter of the following requirements set forth in Medicare Benefit Policy Manual, chapter 1 § 10: (1) the 24-hour requirement for inpatient admissions, (2) that two of the four factors for consideration when making the inpatient decision pertain to diagnostic studies, and (3) that inpatient care is unnecessary when such studies can be completed in less than 24 hours. Dr. Polansky never received any direct feedback. Instead, a few hours later he was instructed that he could not attend a monthly regulatory affairs meeting attended by senior management. Dr. Polansky was also forbidden to discuss his concerns with members of the EHR regulatory affairs team or his former colleagues at the Medicare program.

183. Having received no response to his memo from McCarter, Dr. Polansky forwarded his memo to EHR's President and Chief Executive Officer, Tom Mercer, in the evening on February 9, 2012, requesting an urgent meeting:

> I'd like to get together in the near term. I believe there may be significant time sensitive risks to the brand and our clients that may benefit from your evaluation and input. I am forwarding an email and key attachments that I hope will provide an introduction. I believe it essential that we objectively evaluate the state of the art in compliance with inpatient vs. observation decision making. I have found it extremely difficult to get Tom [McCarter]/ Mark [Stabile] to engage productively in the discussion. The response is typically hostile and appears to have led to a cascade of efforts to isolate me from the enterprise. As examples, today, without explanation, my participation in the Clinical Regulatory Committee was withdrawn. Last week, I was instructed not to contact Regulatory Affairs.

Dr. Polansky's request for the meeting was not granted.

184. Moreover, shortly after his arrival at EHR in or around December 2011, Dr. Polansky had multiple discussions with CCO McCarter concerning how to interpret Medicare requirements, during which Dr. Polansky repeatedly suggested to McCarter that EHR should engage CMS's leadership in an open discussion on the regulatory requirements for inpatient versus outpatient services. McCarter told Dr. Polansky that [redacted] In late 2011, Dr. Polansky was also told by Tom Mercer, who at the time was Vice President of Operations, that EHR's strategy [redacted]

**C. EHR Is Causing Hospitals Across America To Present False Inpatient Claims**

185. Ultimately, the EHR Logic, including its fraudulent case review criteria, repeatedly cause the conversion of what should be outpatient claims to inpatient claims. This conversion has led to an epidemic of one and two day inpatient hospital admissions. These short stay patients typically are determined not to have acute conditions requiring hospital admission based on diagnostic evaluation, have responded quickly to therapeutic interventions, or have undergone an uncomplicated outpatient surgical procedure.

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[9] EHR deviated from this general rule when it drafted a letter to a MAC, Highmark, in 2011 in which it attempted to mislead a Highmark medical director that observation services cannot be ordered for patients following outpatient surgery. EHR in part uses this argument to conclude that all [redacted] outpatient cases must be admitted to inpatient status.

186. These claims, which are based on fraudulent billing, are not payable and are false claims. Inpatient status was neither reasonable and necessary, nor provided in the most economical setting.

187. By knowingly supplying hospitals with false inpatient certifications that it knows will cause the hospitals to present false or fraudulent inpatient claims for payment to the Government Payers, EHR violated 31 U.S.C. § 3729(a)(1)(A) (pre-FERA 31 U.S.C. § 3729(a)(1)).

188. In addition, by knowingly making false records or statements (*i.e.*, the inpatient certifications) material to the false or fraudulent inpatient claims that hospitals submitted to the Government Payers, EHR violated 31 U.S.C. § 3729(a)(1)(B) (pre-FERA 31 U.S.C. § 3729(a)(2)).

189. For purposes of FCA liability, a defendant "causes" an intermediary to present a false or fraudulent claim for payment to the government where the defendant's fraudulent conduct was a "substantial factor" in bringing about the submission of the false or fraudulent claim and the intermediary's submission of the claim was a "normal consequence" of the defendant's fraudulent conduct. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004); *accord United States ex rel. Bergman v. Abbott Labs.*, Civ. No. 09-4264, 2014 WL 348583, at *9 (E.D. Pa. Jan. 30, 2014); *United States ex rel. Galmines v. Novartis Pharma. Corp.*, Civ. No. 06-3213, 2013 WL 2649704, at *11 (E.D. Pa. June 13, 2013). And, where the intermediary knowingly presents the false claim and has therefore violated the FCA, the defendant is still responsible for causing the submission of the false or fraudulent claim. *See id.* In such cases, both the defendant and the intermediary have violated the FCA and both are liable to the government – jointly and severally. In other words, while the intermediary has

defrauded the government, this does not break the causal chain between the defendant's fraudulent act and the harm suffered by the government.[10]

190. That EHR's fraudulent inpatient certifications are a substantial factor in hospitals' submission of false inpatient claims to the Government Payers is evidenced by:

(a) **Hospitals' contracts with EHR**: The very reason hospitals contract with EHR is to give EHR responsibility for performing the second level review of those cases that fail the UM Criteria for inpatient status and thereby provide the hospital with a basis (EHR's inpatient certification) for billing those cases as inpatient – or as EHR calls it a basis to create "revenue integrity";

(b) **EHR's certifications are routinely determinative of the billing status a hospital assigns to a case for government reimbursement purposes**: In the vast majority of instances in which EHR certifies a case for inpatient status after the case has failed the inpatient UM Criteria, the hospital defers to EHR's inpatient certification and bills that case as inpatient. As noted, it is rare that a hospital does not follow the EHR certification. In fact, as a service to the hospital to track physician compliance with EHR decisions, EHR produces reports that identify the rate of concordance with its decisions as well as identify cases and physicians who deviate. From Dr. Polansky's experience, deviation from EHR certifications is generally restricted to cases where operational delays have led to the EHR certification arriving after patient discharge.

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[10] The government has successfully prosecuted numerous FCA cases against defendants, like EHR, who caused an intermediary to present false claims for payment to the government health care programs. For example, the government has recovered tens of millions of dollars against Kyphon Inc. for causing hospitals to present false inpatient claims. *See, e.g.*, May 22, 2008 Dept. of Justice Press Release Announcing "Medtronic Spine, Formerly Kyphon Inc., To Pay U.S. $75 Million To Resolve Allegations Of Defrauding Medicare."

(c) **Hospitals pay EHR a significant sum to perform the inpatient reviews:** Hospitals would not pay [redacted] per EHR inpatient review (*see* paragraph 102 above) if they did not give substantial weight to EHR's inpatient certifications;

(d) **Hospitals incorporate EHR's inpatient certifications into patients' permanent medical record** and, in turn, pursuant to 42 C.F.R. § 412.46(b) (2013), the "physician's order and certification [for inpatient status is] evaluated in the context of the evidence in the medical record";

(e) **Hospitals effectively outsource their second level physician advisor utilization review function, a function that is mandated by CMS requirements (*see* paragraph 72 above), to EHR**; and

(f) **Hospitals enforce the "Compliance Warranty" provision in their agreements with EHR**: EHR's "Compliance Warranty" only applies to denials for which EHR had conducted a concurrent review and provided an inpatient certification that the hospital adopted (*see* paragraph 97 above).

191. An example of a hospital completely relying on EHR's inpatient certifications is [redacted] In 2011, MAC, National Government Services, Inc. ("NGS"), performed an on-site review of [redacted] inpatient claims for Medicare payment. In correspondence to [redacted] head of operations, NGS determined that in multiple instances, due to its reliance upon incorrect EHR billing certifications, [redacted] had improperly billed for inpatient payment. In its "general findings," NGS concluded:

[redacted]

[redacted] (Emphasis added).

192. The "external consultant" NGS referenced was defendant EHR. Notably, on December 28, 2011, [redacted] sent to EHR copies of the medical charts for the seven cases that NGS had denied as improper. One of these seven cases is described in paragraphs 142 through 145 above.

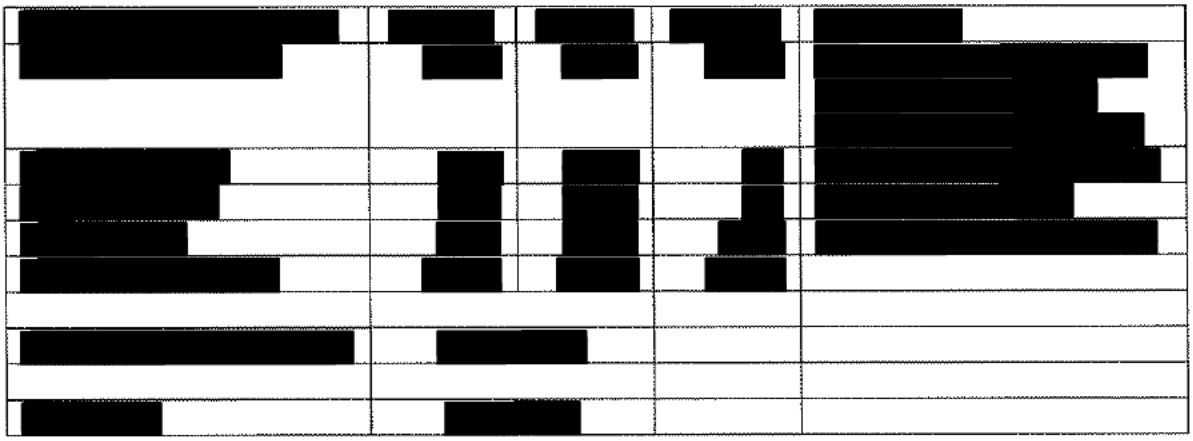
***EHR's own documents substantiate the pivotal role its false certifications routinely play in dramatically increasing inpatient hospital claims payments***

193. EHR itself highlights the dramatic causal impact that its inpatient certifications have had in converting thousands upon thousands of outpatient cases to inpatient status in its interactions with clients and prospective clients:

(a) In late 2007 or early 2008, EHR presented to client [redacted] located in Charlotte, North Carolina an overview of the impact EHR had on [redacted] inpatient admissions and financial results for the prior 12 month period. The numbers tell the story of the impact of EHR's case review criteria to convert substantial numbers of cases that fail the widely recognized and available screening criteria to inpatient certification. [redacted]

(b) In June 2011, EHR gave a presentation to hospital management at [redacted] to quantify the impact of EHR's certification services on [redacted] Medicare claims for payments. After matching cases [redacted] referred to EHR with the resultant claim submitted to Medicare, EHR concluded that it had converted enough outpatients to inpatient billing status to [redacted] For all the claims EHR certified over the period, [redacted]

(c) In mid-2010, top EHR management, including then President and CEO Robert Corrato, gave a PowerPoint presentation to management of the [redacted] highlighting the material impact that EHR's certification services had upon [redacted]



(d) In or around the second half of 2010, EHR prepared a PowerPoint presentation given to management at [redacted]

[redacted] highlighting the impact EHR's certifications had had upon [redacted] billing designations and its revenue stream at mid-year. According to the presentation, [redacted]

194. EHR was only able to report these fraudulently inflated outpatient to inpatient conversion rates to hospitals because it knew that its inpatient certifications caused the conversions – *i.e.*, the hospitals relied on EHR's certifications in billing these cases, which failed the UM Criteria for inpatient status, as inpatient admissions.

195. Another example of a hospital that received a revenue windfall by relying upon EHR's inpatient certifications is Bon Secours St. Francis Health System in Greenville, South Carolina. In a January 2012 article published in *Hospital Case Management*, Bon Secours St. Francis praises EHR for successfully appealing and recovering nearly $2 million in inpatient

[11] "MC" refers to Medicare; "MA" refers to Medicaid.